

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-00358-JL

Mutual Pharmaceutical
Company, Inc.

SUMMARY ORDER

Attached are the court's rulings on Mutual's objections to the deposition testimony of one of Bartlett's potential witnesses, Andrea Werynski, and the court's rulings on Bartlett's objections to Mutual's counter-designated deposition testimony of witnesses Werynski, Robert Dettery, Dr. Claes Dohlman, and Dr. Nam Heui Kim, all of whom have been deemed unavailable to testify at trial under Rule 32(a)(4) of the Federal Rules of Civil Procedure (see doc. 275).

SO ORDERED.



Joseph N. Laplante
United States District Judge

Dated: August 18, 2010

cc: Bryan Ballew, Esq.
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Witness_ Andria Werynski - Vol. 1.txt: 1:1 - 1:21

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

2

3

4 KAREN L. BARTLETT and
GREGORY S. BARTLETT,

5 Plaintiffs,

Case No.: 08-cv-358-JL

6 Judge Joseph N. Laplante

V

7

8 MUTUAL PHARMACEUTICAL
COMPANY, INC. and UNITED
9 RESEARCH LABORATORIES, INC.,
Defendants.

10

11

12 Oral deposition of ANDRIA

13 WERYNSKI, taken at the law offices of
14 Segal, McCambridge, Singer & Mahoney,
15 Ltd., United Plaza, 30 South 17th
16 Street, Suite 1700, Philadelphia,
17 Pennsylvania, on Tuesday, September 1,
18 2009, at 9:08 a.m., before Jennifer L.
19 Bermudez, a Registered Professional
20 Reporter, and Notary Public, pursuant to
21 notice.

Witness_ Andria Werynski - Vol. 1.txt: 3:6 - 4:1

Q. Please state your name for the
7 record.

8 A. Andria Werynski.

9 Q. And what do you do for a living,
10 Ms. Werynski?

11 A. I'm the manager of regulatory
12 affairs.

13 Q. With who?

14 A. URL Mutual.

15 Q. And since when have you held that
16 title, please?

17 A. Approximately September 2007.

18 Q. What was your title before that?

19 A. Assistant manager, regulatory
20 affairs.

21 Q. When did you obtain that title?

22 A. Approximately August 2006.

23 Q. And what did you do before that?

24 A. Regulatory affairs associate.

25 Q. When did you obtain that title?

00004

1 A. December 2003.

Witness_ Andria Werynski - Vol. 1.txt: 4:6 - 4:8

Q. So you are coming up on your sixth
7 anniversary at URL Mutual?

8 A. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 4:15 - 6:7

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Q. And do you have any advance
16 degrees, Ms. Werynski?

17 A. I have a Master's in quality
18 assurance and regulatory affairs.

19 Q. Is your employer URL Mutual?

20 A. Yes.

21 Q. Has that been true since December
22 2003?

23 A. Yes.

24 Q. Which entities do you do
25 regulatory affairs for?

00005

1 A. Mutual Pharmaceutical Company.

2 Q. Any others?

3 A. United Research Laboratories.

4 Q. Just those two?

5 A. Yes.

6 Q. What about AR Holdings?

7 A. Yes. That's correct. We are the
8 regulatory agent for AR Holdings.

9 Q. What does that mean?

10 A. AR Holdings doesn't own any
11 applications -- or I'm sorry. They own
12 the applications. They are transferred,
13 the brands are transferred to them upon
14 approval.

15 Q. And those are just the four NDAs?

16 A. Yes.

17 Q. And an NDA is for a brand name
18 drug?

19 A. Correct. And, actually, I don't
20 believe they hold the Bactrim NDA. I
21 think they just hold the --

22 Q. And when you say "they," who is
23 the pronoun you are --

24 A. AR Holding.

25 Q. Who holds the Bactrim brand name?
00006

1 A. Mutual.

2 Q. So Mutual holds one NDA,
3 therefore?

4 A. Correct.

5 Q. And AR Holdings holds the other
6 three NDAs?

7 A. Yes.

Objection (5:25 to 6:7):
-402

Ruling: Overruled. Some limited reference to
other drugs that Mutual manufactures is
permissible as background information.

Witness_ Andria Werynski - Vol. 1.txt: 8:13 - 9:10

Q. How many of Mutual's ANDAs are
14 presently marketed and distributed?

15 A. I don't know.

16 Q. What's your best estimate?

17 A. 30.

18 Q. And how many ANDAs or generic
19 applications does Mutual hold, to your
20 best estimate?

21 A. 220.

22 Q. How many of those 220 do you
23 actively work on since December of '03?

24 A. All of them.

25 Q. Is it correct that you file annual

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00009

1 reports and what's called periodic
2 report on all 220 of them?
3 A. Yes.
4 Q. And, in other words, the fact that
5 you are distributing them or not, the 30
6 versus the 220, is it correct to state
7 that does not have a difference in terms
8 of when or how often either annual
9 reports or periodic reports are filed?
10 A. Yes.

Objection:
-402

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 12:9 - 12:22

Q. From December '03,
10 chronologically, back to present,
11 please, tell me who were the persons you
12 reported to since you began, please.
13 A. As a research associate and an
14 assistant manager, I reported to Sherry
15 Schultz.
16 Q. And since you became the manager
17 of RA, you have reported to
18 Ms. Phillips?
19 A. No. I reported to Robert Dettery
20 until Ms. Phillips started.
21 Q. When did Ms. Phillips start?
22 A. Approximately July 2008.

Witness_ Andria Werynski - Vol. 1.txt: 13:3 - 13:6

Did you report to
4 Mr. Dettery immediately when you became
5 the manager of RA?
6 A. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 13:11 - 14:8

Q. What is Sherry Schultz's title,
12 please?
13 A. Manager, regulatory affairs.
14 Q. So you reported to her from
15 December '03 through approximately
16 September '07?
17 A. Correct.
18 Q. Who did Ms. Schultz report to when
19 you reported to her?
20 A. Robert Dettery.
21 Q. Do you presently understand that
22 Ms. Phillips reports to Mr. Dettery?
23 A. Yes.
24 Q. The entire time you have been with
25 the URL and Mutual companies, has
00014

1 Mr. Dettery been the top person in
2 charge of all regulatory affairs
3 matters?
4 A. Yes.
5 Q. From the day you arrived through
6 today, ultimately, the buck has always
7 stopped with Mr. Dettery in terms of
8 regulatory affairs decisions, correct?

Objection (14:5 to 14:15):
-Argumentative
-Vague

Ruling: Overruled.

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Witness_ Andria Werynski - Vol. 1.txt: 14:12 - 14:18

THE WITNESS: No. I mean, he
13 reports to people as well, above him.
14 BY MR. JENSEN:
15 Q. Yes, ma'am.
16 But there's no one above him in
17 regulatory affairs, correct?
18 A. Correct.

Witness_ Andria Werynski - Vol. 1.txt: 15:12 - 15:21

Q. Since you have been there in 2003,
13 has anyone ever, to your knowledge,
14 changed any decision Mr. Dettery has
15 made regarding any regulatory affairs
16 matter?
17 A. No.
18 Q. So, to your knowledge, since you
19 have been there, the regulatory affairs
20 buck has always stopped with
21 Mr. Dettery, correct?

Witness_ Andria Werynski - Vol. 1.txt: Page 16, Line 1

A. To my knowledge, yes.

Witness_ Andria Werynski - Vol. 1.txt: 16:13 - 16:17

Your best recollection is you have
14 never had a conversation with anyone at
15 the FDA regarding anything to do with
16 sulindac; is that true?
17 A. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 16:22 - 17:20

Other than being
23 involved potentially in the work of an
24 annual report or a periodic report for
25 sulindac, would that encompass all of
00017
1 your involvement with sulindac since you
2 have been with URL Mutual in December
3 2003?
4 A. I don't know.
5 Q. What other involvement might you
6 have had when you say "I don't know," I
7 might have done other things?
8 A. A supplement to make a change.
9 Q. Yes, ma'am.
10 Anything else?
11 A. No.
12 Q. So periodic reports, annual
13 reports or supplements to make a change,
14 if you were involved in those, would
15 have been your only involvement
16 regarding anything to do with sulindac
17 from your arrival in December 2003 to
18 date?
19 Do I now have that correctly

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20 stated?

Witness_ Andria Werynski - Vol. 1.txt: 17:24 - 18:13

THE WITNESS: Yes.

25 BY MR. JENSEN:

00018

**1 Q. And before we might hypothetically
2 look at any annual reports or quarterly
3 reports, do you presently, sitting here,
4 have a recollection of being involved in
5 any quarterly, annual or supplemental
6 reports regarding sulindac?**

7 A. Yes.

**8 Q. And when do you best recollect you
9 were first so involved?**

10 A. Maybe 2008.

**11 Q. Do you believe you were first
12 involved with sulindac in 2008 in any
13 way, shape or form?**

Objection (18:1 to 18:23):
-402 (as to time and issue)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 18:16 - 18:23

THE WITNESS: Yes.

17 BY MR. JENSEN:

**18 Q. And then why is it your belief
19 that you were first involved in sulindac
20 in the year 2008?**

**21 A. Because I became responsible for
22 reviewing periodic reports prior to
23 submission.**

Witness_ Andria Werynski - Vol. 1.txt: 19:23 - 20:2

Prior to 2008, would your

**24 involvement with sulindac have been
25 limited to helping out on an as-needed
00020**

**1 basis with any filings prior to that
2 year?**

Objection (19:23 to 20:6):
-402 (as to time and
issue)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: Page 20, Line 6

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 23:3 - 23:6

**Q. Prior to 2008, you never had any
4 job function that involved review of
5 annual reports or quarterly or annual
6 periodic reports for sulindac, correct?**

Objection (23:3 to 26:3):
-402 (as to time and issue)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 23:12 - 23:21

**A. I don't know when the time frame
13 was that I began to review annual
14 reports or periodic reports.**

**15 Q. Okay. And is that true for all
16 drugs, or you just don't remember for
17 sulindac?**

18 A. All drugs.

19 Q. When would it have been? Would it

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20 have been in relation to the change in
21 title, change in responsibility?

Witness_ Andria Werynski - Vol. 1.txt: 23:24 - 25:25

THE WITNESS: I guess when I
25 became an assistant manager.
00024

1 BY MR. JENSEN:

2 Q. Okay. Which was August '06?

3 A. Yes.

4 Q. Let's use that as a time frame,
5 then.

6 Prior to August '06, is it correct
7 that you never had a job responsibility
8 to review any annual reports?

9 A. Yes.

10 Q. Why did you review the 2007
11 periodic reports for sulindac when you
12 last reviewed them?

13 A. It's in my job function.

14 Q. And did you review them prior to
15 them being filed?

16 A. Yes.

17 Q. And do you do that for all
18 periodic reports since about 2007 prior
19 to them being filed?

20 A. Yes.

21 Q. You review them for completeness
22 and accuracy before they are filed?

23 A. Yes.

24 Q. Who prepares them for you, in
25 relation to sulindac, since about 2007
00025

1 before you review them?

2 A. A contract research company called
3 Prosar.

4 Q. Did you ever review periodic
5 reports for sulindac prior to Prosar
6 being involved?

7 A. No.

8 Q. Is it your understanding that
9 Prosar does surveillance of the medical
10 literature for Mutual's ANDAs/generic
11 drugs?

12 A. Yes.

13 Q. What is your understanding of when
14 Prosar, on behalf of Mutual, started
15 doing surveillance of the medical
16 literature for Mutual's generic ANDA
17 drugs?

18 A. When?

19 Q. Yes, ma'am.

20 A. 2006.

21 Q. Is it your understanding that,
22 prior to 2006, neither Mutual, nor no
23 one on Mutual's behalf, ever conducted
24 surveillance of the medical literature
25 regarding its generic Mutual drugs?

Witness_ Andria Werynski - Vol. 1.txt: Page 26, Line 3

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THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 26:16 - 27:1

Q. Other than the fact that a Mutual
17 affiliated company first started
18 marketing a brand product, and you also
19 told me Mutual markets one brand
20 product, other than those facts, can
21 you, Ms. Werynski, cite any other fact
22 in support of the reason or reasons why
23 Mutual for the first time in 2006
24 started, through somebody else, having
25 medical literature surveillance done for
00027
1 its generic, also known as ANDA drugs?

Objection (26:16 to 29:6):
-402
-403
-407 (Prescription date 12/04)

Ruling: Sustained (through line 31:2).
Mutual's failure to review the medical
literature and to report adverse safety
information to the FDA is no longer relevant
to the case, now that Bartlett's claims for
negligence and enhanced compensatory
damages have been dismissed.

Witness_ Andria Werynski - Vol. 1.txt: 27:6 - 27:14

THE WITNESS: No.
7 **BY MR. JENSEN:**
8 Q. As stated in the affirmative, the
9 only reason you know that Mutual started
10 doing surveillance of the medical
11 literature in 2006 is because at about
12 that time Mutual, or its affiliated
13 companies, started selling brand name
14 drugs; is that correct?

Witness_ Andria Werynski - Vol. 1.txt: 27:18 - 28:1

THE WITNESS: We implemented
19 the process in association with the
20 branded product.
21 **BY MR. JENSEN:**
22 Q. And other than that fact, you
23 can't think of any other reason why
24 Mutual started doing this for its
25 generic drugs as well?
00028
1 A. No.

Witness_ Andria Werynski - Vol. 1.txt: 28:5 - 28:15

Q. No, you cannot. Correct?
6 A. No, I cannot.
7 Q. Thank you.
8 And since Mutual began, through
9 somebody else, doing medical literature
10 surveillance for its generic, also known
11 as ANDA drugs, when a decision is made
12 that the medical literature warrants
13 reporting under the regulations, since
14 that time such medical literature has
15 been reported, correct?

Witness_ Andria Werynski - Vol. 1.txt: 28:18 - 29:3

THE WITNESS: Yes.
19 **BY MR. JENSEN:**
20 Q. In other words, before 2006,
21 Mutual, on behalf of its ANDA drugs,

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22 never looked for nor provided any
23 medical literature to the FDA for its
24 generic ANDA drugs, and after about
25 2006, they both looked for, through
00029

1 somebody else, and when it warranted,
2 gave medical literature to the FDA for
3 the first time, correct?

Witness_ Andria Werynski - Vol. 1.txt: Page 29, Line 6

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 29:23 - 30:7

Q. As a person who has a career in
24 regulatory affairs, Ms. Werynski, the
25 proposition of providing medical
00030
1 literature to the FDA provides them
2 information in which they can assess and
3 make determinations whether that
4 information warrants or does not warrant
5 potentially providing new information in
6 a package insert and/or to physicians
7 through other means?

Witness_ Andria Werynski - Vol. 1.txt: Page 31, Line 2

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 32:16 - 32:21

Q. And don't you think it's good that
17 they provided that ability by you giving
18 them medical literature?
19 Don't you think it's a good thing
20 that Mutual now chooses to do this, give
21 them medical literature for its drugs?

Witness_ Andria Werynski - Vol. 1.txt: 32:25 - 33:8

THE WITNESS: No.
00033

1 BY MR. JENSEN:

2 Q. No, you don't think it's a good
3 thing?

4 A. No.

5 Q. So you think it's a bad thing that
6 Mutual has now chosen to start providing
7 medical literature to the FDA for its
8 generic drugs?

<p>Objection (32:16 to 34:3): -Argumentative -407 -Calls for opinion from non-retained expert</p>

<p>Ruling: Sustained.</p>

Witness_ Andria Werynski - Vol. 1.txt: 33:12 - 34:3

THE WITNESS: I don't think
13 it's a bad thing.

14 BY MR. JENSEN:

15 Q. Well, you just said that you don't
16 think it's a good thing. So what is it?

17 A. I don't think that it helps.

18 Q. You don't think that it helps?

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19 A. No.

20 Q. And why is that the case?

21 A. Because the brand companies also
22 do literature searches.

23 Q. But you assume that the brand
24 companies provide medical literature to
25 the FDA, you don't have personal
00034

1 knowledge that they do? You never see
2 their filings, correct?

3 A. Correct.

Witness_ Andria Werynski - Vol. 1.txt: 34:7 - 34:15

Q. So, if the brand name companies
8 are hypothetically providing the medical
9 literature to the FDA and they are
10 assessing it, in that example, a second
11 copy would do nothing; but if they are
12 not, then you might be providing some
13 new information, right?
14 You don't know whether they are,
15 right?

Objection (34:7 to 34:19):
-Argumentative
-Calls for opinion
testimony

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 34:19 - 35:2

THE WITNESS: Yes.

20 BY MR. JENSEN:

21 Q. Hence, because a generic company
22 never knows whether a brand name company
23 is actually providing medical literature
24 to the FDA, don't you agree that it's a
25 good thing that Mutual is now for the
00035

1 first time giving medical literature to
2 the FDA for its generic drugs?

Objection (34:21 to 37:1):
-Argumentative
-407
-Calls for opinion testimony

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 35:7 - 35:16

THE WITNESS: Yes.

8 BY MR. JENSEN:

9 Q. Don't you think, because you now
10 agree it's a good thing that Mutual for
11 the first time in 2006 has started
12 providing medical literature to the FDA
13 for its generic drugs, that it is a
14 better way of operating than it did in
15 the past for the reasons you just agreed
16 with?

Witness_ Andria Werynski - Vol. 1.txt: 35:22 - 36:4

THE WITNESS: Yes.

23 BY MR. JENSEN:

24 Q. How much of your time do you best
25 estimate, Ms. Werynski, is spent
00036

1 assessing medical literature and whether
2 or not it's properly reportable for
3 either NDA or ANDA drugs?

4 A. None.

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Witness_ Andria Werynski - Vol. 1.txt: 36:8 - 36:11

Q. Does Prosar both find and make
9 recommendations to Mutual/URL on the
10 reportability of the medical literature
11 it finds?

Witness_ Andria Werynski - Vol. 1.txt: Page 36, Line 14

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 36:19 - 36:22

To your knowledge, does Prosar
20 make not only recommendations, but
21 decisions as to which medical literature
22 is reportable for Mutual?

Witness_ Andria Werynski - Vol. 1.txt: Page 37, Line 1

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 37:21 - 37:25

Q. To your knowledge, has anyone at
22 Mutual ever countermanded, reversed,
23 vetoed a Prosar decision as to what
24 medical literature was reportable for a
25 generic drug?

Objection (37:21 to 38:5):
-407 (Prosar involved only
after Rx date of 12/04)
-Argumentative
-Foundation

Ruling: Sustained (through line 43:13).

Witness_ Andria Werynski - Vol. 1.txt: Page 38, Line 5

THE WITNESS: No.

Witness_ Andria Werynski - Vol. 1.txt: 43:9 - 43:13

Have you ever been involved in
10 making a decision as to what any medical
11 publication should be or should not be
12 reported to the FDA?
13 A. No.

Witness_ Andria Werynski - Vol. 1.txt: 44:25 - 45:6

Q. Is it also correct to state that
00045
1 you don't know of any employee in any of
2 the Mutual entities who has ever made
3 medical literature reportability
4 decisions, rather, to your knowledge,
5 all such decisions have been made by
6 persons at Prosar?

Objection (44:25 to 45:11):
-407 (Prosar involved only
after Rx date of 12/04)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: Page 45, Line 11

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 48:19 - 48:25

Q. Excluding that instance of
20 cosuspect drugs, is it correct that
21 generic companies never see the filings

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22 of their brand name counterparts, so
23 they don't know whether the brand name
24 counterparts are providing medical
25 literature to the FDA or not?

Witness_ Andria Werynski - Vol. 1.txt: Page 49, Line 5

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 51:10 - 51:19

Is it correct to state that you
11 have never heard that anyone, before you
12 got involved with sulindac, between 1991
13 and 2004, ever, A, filed a citizen's
14 petition, B, did a CBE labeling change,
15 or, C, made any advocacy attempts that
16 any risk information be strengthened or
17 enhanced on the sulindac label in that
18 13-year time period between 1991 and
19 2004?

Objection (51:10 to 53:4):
-Compound, vague
-Misleading (unclear which
question is answered)
-402 (time)

Ruling: Sustained. Mutual's failure to
advocate a stronger warning is not relevant to
whether its warning in place at the time of
Bartlett's prescription avoided an unreasonable
risk of danger, or to any other issue in the case.

Witness_ Andria Werynski - Vol. 1.txt: 51:24 - 52:7

THE WITNESS: I don't know if
25 anyone made any labeling changes in 13
00052
1 years without looking at the
2 correspondence.
3 BY MR. JENSEN:
4 Q. But you do know what you have
5 heard of, and you have never heard that
6 that occurred, correct, any of those
7 three things?

Witness_ Andria Werynski - Vol. 1.txt: 52:10 - 52:25

THE WITNESS: Correct.
11 BY MR. JENSEN:
12 Q. And let's talk more about what you
13 know from either reading it or hearing
14 about it.
15 To the best of your knowledge,
16 Mutual has never for any of its generic,
17 also known as ANDA drugs, done any of
18 those three things, A, file a citizen's
19 petition, B, did a changes being
20 effected label change or, C, made any
21 advocacy to the FDA for enhanced or
22 strengthened risk information at any
23 time, a time way before you began in
24 1991 through today in August -- or
25 September of 2009, correct?

Witness_ Andria Werynski - Vol. 1.txt: Page 53, Line 4

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 55:6 - 55:10

to the extent anyone believed
7 or testified that you only need to keep

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8 periodic ADD reports for a year or two
9 after the expiration of the underlying
10 product, that would be incorrect, right?

Witness_ Andria Werynski - Vol. 1.txt: 55:14 - 55:23

Objection (55:6 to 55:23):
-402

Ruling: Sustained.

THE WITNESS: Are you talking
15 about periodic reports, adverse drug
16 reports?
17 BY MR. JENSEN:
18 Q. Yes.
19 A. Yes, that would be incorrect.
20 Q. The regulations very clearly state
21 that such documentation needs to be kept
22 for ten years, correct?
23 A. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 57:2 - 57:8

Q. What was the annual reporting
3 period for sulindac, from what month to
4 what month?
5 A. I would have to see when it was
6 approved.
7 Q. In April 1991.
8 A. Then it's April 1st to March 31st.

Witness_ Andria Werynski - Vol. 1.txt: 57:13 - 57:19

Q. I'm going to show you an article,
14 here it is, it's KB 2769. And we are
15 going to start with the date of it.
16 And do you see the article is
17 dated February 13, 2003? The lower
18 left. I highlighted it.
19 A. Yes.

Objection:
-402

Ruling: Sustained. Mutual's notice of the Mockenhaupt study is no longer relevant, since Bartlett's negligence and failure-to-warn claims have been dismissed.

Witness_ Andria Werynski - Vol. 1.txt: 59:24 - 60:3

If,
25 hypothetically, it was decided this was
00060
1 a 15-day report, when would this report,
2 published on February 13th, 2003, have
3 been reported?

Objection (59:24 to 60:9):
-Improper hypothetical
-Improper assumption of facts
-Calls for expert opinion

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 60:8 - 60:9

Q. The one starting at 2769.
9 A. April 2003.

Witness_ Andria Werynski - Vol. 1.txt: 61:20 - 61:25

The annual report needs to be
21 filed every year within 60 days of the
22 anniversary approval?
23 A. 60 days?
24 Q. Yes, ma'am.
25 A. Yes.

Objection:
-402

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 62:16 - 62:22

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Q. So, again, roughly, if it's April
17 17, '91 was the approval date, we are
18 talking approximately June 17th, give or
19 take a couple days, that the periodic
20 annual reports would need to be filed,
21 correct?
22 A. Yes.

Objection:
-402

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 65:20 - 65:23

Q. How, if at all, were you involved
21 with the 2009 changes being effected
22 label change that Mutual for the first
23 time did for one of its NDA drugs?

Objection (65:20 to 68:10):
-402 (questions relate to
NDA product)
-403
-407 (Rx date 12/04)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 66:2 - 66:12

Q. Let me add the risk of
3 thrombocytopenia to Qualaquin.
4 A. Oh, I was involved in that.
5 Q. How so?
6 A. I prepared the submission.
7 Q. Were you involved at all in
8 determining whether the medical
9 information warranted the unilateral CBE
10 label change that Mutual was submitting
11 to the FDA before the FDA had even
12 approved the label change?

Witness_ Andria Werynski - Vol. 1.txt: 66:16 - 66:24

THE WITNESS: No.
17 BY MR. JENSEN:
18 Q. And I did have an assumption in my
19 question.
20 Is it correct to state that the
21 2009 label change for Qualaquin was one
22 that Mutual unilaterally instituted
23 before the FDA had approved that label
24 change?

Witness_ Andria Werynski - Vol. 1.txt: 67:2 - 67:17

THE WITNESS: What do you
3 mean by "unilaterally"?
4 BY MR. JENSEN:
5 Q. Unilaterally means taking action
6 on your own without someone else's
7 authority or approval.
8 A. So you are asking did we implement
9 the change prior to updating the
10 approval?
11 Q. Yes.
12 A. Yes.
13 Q. And that's what a changes being
14 effected label change is, it allows, in
15 this exact circumstance, Mutual to make
16 a label change before they get the FDA's
17 approval, correct?

Witness_ Andria Werynski - Vol. 1.txt: 67:22 - 68:5

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THE WITNESS: Yes.

23 BY MR. JENSEN:

24 Q. Who were the persons involved in
25 determining that that action needed to
00068

1 be taken, i.e., that the medical facts
2 and science warranted the need to make
3 that label change before the FDA even
4 assessed whether it needed to be
5 changed?

Witness_ Andria Werynski - Vol. 1.txt: 68:9 - 68:10

THE WITNESS: Upper
10 management.

Witness_ Andria Werynski - Vol. 1.txt: 72:13 - 72:17

Q. Do you recall that the risk
14 information regarding thrombocytopenia
15 was enhanced and moved in the label to a
16 different location?
17 A. Yes.

Objection:
-402 (does not relate to
Sulindac)
-407 (after 12/04)

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 73:17 - 73:22

Q. Is that the first time in your
18 career in 2009 that you had ever been
19 involved with a unilateral label change,
20 again, defining that as the drug company
21 making a change to the label before the
22 FDA has approved that label change?

Objection:
-402
-407
-No answer designated

Ruling: Sustained (through line 74:9).

Witness_ Andria Werynski - Vol. 1.txt: 74:3 - 74:16

Q. Have you ever been involved in
4 such a label change with any of the
5 Mutual entities before that?
6 A. When we do RLD updates for generic
7 drugs, that's via a changes being
8 effected supplement.
9 Q. Understood.
10 Let me ask you this way: Was the
11 2009 CBE label change that you were
12 involved in the first such label change
13 you had ever been involved in to
14 enhance, add to or strengthen risk
15 information in a label in your career at
16 any of the Mutual entities?

Objection (74:10 to 75:4):
-402
-407

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 74:21 - 75:4

THE WITNESS: Associated

22 outside of RLD updates, yes.

23 BY MR. JENSEN:

24 Q. And the caveat you are making is,
25 there might be an RLD update that might
00075

1 enhance risk information, but it was not
2 one that Mutual unilaterally made a
3 decision to make those changes?
4 A. Correct.

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Witness_ Andria Werynski - Vol. 1.txt: 75:7 - 75:12

Is it correct to state that you
 8 have never been involved at Mutual with
 9 any changes being effected label change
 10 to enhance or increase or add to risk
 11 information for any generic, also known
 12 as ANDA drug, at any time? Correct?

Objection:

-Plaintiff did not designate the
 answer; Plaintiff misunderstood the
 answer and designated a later
 answer after confusing the witness.
 RLD update is done for GENERIC
 drugs. Question becomes
 nonsensical when plaintiff says
 "that's excluded from my question".

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: Page 76, Line 5

THE WITNESS: Yes.

Objection:

-Same as 75:7 to 75:12

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 77:24 - 78:14

Q. Are you aware from any source that
 25 the Honorable Joseph Laplante, the
 00078

1 presiding judge in this case, has ruled
 2 against Mutual's position that ANDA,
 3 also known as generic drug holders,
 4 cannot change their labels to add to or
 5 strengthen risk information?
 6 A. Yes.

7 Q. Are you aware that Karen
 8 Bartlett's prescribing physician, who
 9 prescribed her sulindac, has testified
 10 that if there were warnings in place
 11 about a higher risk of SJS and TEN from
 12 sulindac than other NSAIDs, he would
 13 never have prescribed her the sulindac
 14 that he did?

Objection (77:24 to 78:19):

-402
 -Argumentative

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 78:19 - 79:16

THE WITNESS: No.

20 BY MR. JENSEN:

21 Q. Can you flip back to the article,
 22 please, that starts at page 2769.

23 Tell me when you are there.

24 A. Okay.

25 Q. Thank you.

00079

1 And then flip to 2771. Tell
 2 me when you are there.

3 A. Okay.

4 Q. And under Table 1 it gives a
 5 relationship between various NSAIDs and
 6 their relative risk in relation to SJS
 7 and TEN.

8 And if you follow down the left
 9 column, under Drugs, under Ketoprofen,
 10 which is also an NSAID they have no
 11 confirmable risk of SJS and TEN because
 12 the multivariates relative risk is not
 13 statistically significant.

14 Do you see that,

15 Ms. Werynski?

16 A. I see what you are referring to,

Objection (79:1 to 80:9):

-402
 -801
 -802
 -Improper publishing
 -602
 -Foundation, calls for
 speculation
 -Argumentative

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 79:19 - 80:9

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Asking you to assume that that
 20 data means that this study was unable to
 21 confirm a link or relationship between
 22 this NSAID called Ketoprofen on the one
 23 hand and getting SJS or TEN on the other
 24 hand.

25 Asking you to assume that's
 00080

1 correct for purposes of my question.
 2 Is it correct to state, to the
 3 best of your knowledge, the FDA was
 4 never provided this information nor was
 5 Karen Bartlett's physician provided this
 6 information so he could potentially
 7 prescribe Karen Bartlett a safer NSAID
 8 than sulindac before he did prescribe
 9 her sulindac in 2004?

Witness_ Andria Werynski - Vol. 1.txt: 81:19 - 82:3

THE WITNESS: Yes, that's how
 20 I took it.
 21 I don't know what the FDA
 22 knew, and I don't know what Karen
 23 Bartlett's physician knew.
 24 BY MR. JENSEN:
 25 Q. But you do know what Mutual
 00082
 1 provided and, to the best of your
 2 knowledge, Mutual never provided this
 3 information to either of them, correct?

Objection (81:19 to 81:23):
 -402
 -801
 -802
 -Improper publishing
 -602
 -Foundation, calls for
 speculation
 -Argumentative

Ruling: Sustained (through line 82:15).

Witness_ Andria Werynski - Vol. 1.txt: 82:8 - 82:15

THE WITNESS: To the best of
 9 my knowledge, no, they never provided
 10 this particular literature article.
 11 BY MR. JENSEN:
 12 Q. And this information was in the
 13 article we looked at before that came
 14 out in February of 2003. Correct?
 15 A. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 83:7 - 83:17

Q. If I was to represent to you,
 8 Ms. Werynski, that Ms. Bartlett has had
 9 many, many eye surgeries, would that be
 10 news to you?
 11 A. No.
 12 Q. You know that?
 13 A. I saw the Complaint, her medical
 14 records.
 15 Q. When did you first see any of
 16 Karen Bartlett's medical records?
 17 A. May 1st, 2009.

Objection:
 -402
 -Argumentative
 -Characterizes evidence

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 84:11 - 85:4

Q. Tell me what your involvement was
 12 with review of anything to do with Karen

Bartlett v Mutual

13 Bartlett's medical records, how she is
14 doing.

15 A. I received them and I forwarded
16 them to Prosar.

17 Q. Other than that, what other
18 involvement, if any, have you had in
19 reviewing any of Karen Bartlett's
20 medical records?

21 A. Just the review of the 15-day
22 alert report that was submitted.

23 Q. Other than those two things, what
24 other involvement, if any, have you had
25 with Karen Bartlett and/or the review of
00085

1 her medical records?

2 A. Huh-uh.

3 Q. That's it?

4 A. Uh-huh. Yes.

Objection:
-402

Ruling: Sustained as to "and I forwarded them to
Prosar." Otherwise overruled.

Witness_ Andria Werynski - Vol. 1.txt: 87:7 - 87:10

So, I guess I should clarify that
8 I was not aware that she had eye
9 surgeries. I was aware that she had eye
10 injury.

Objection:
-No question designated
-402

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 87:15 - 88:5

Q. Go back to Exhibit 403, please,
16 and find your way to the MedWatch form.
17 Tell me when you have found it,
18 please.

19 A. Uh-huh. Got it.

20 Q. And that is a report that is
21 submitted to the FDA in relation to an
22 adverse event, correct?

23 A. Yes.

24 Q. And this form is the one that was
25 submitted to the FDA in relation to
00088

1 Mutual's receipt of information
2 regarding Karen Bartlett and her adverse
3 event, correct?

4 A. This one is the second report.

5 This is a follow-up report.

Objection:
-402
-403
-801
-802 (contains hearsay within
document for which there is an
exception)
-1002 & 1004 (medical records
are the best evidence)

Ruling: Overruled. The witness may testify
about Mutual's report to the FDA regarding
Bartlett's injuries and the representations that
Mutual made therein, which are party admissions
(Rule 801(d)(2)) and thus are not hearsay. This
is not to say, however, that the entire report is
admissible. For example, the parts referring to
this litigation and the parts referring to Prosar's
literature searches are inadmissible under Rules
401-403, as explained in the court's previous
limine rulings. This court will decide issues
regarding the admissibility of the report at trial.

Witness_ Andria Werynski - Vol. 1.txt: 89:5 - 90:6

Q. Who created the information on
6 Page 9 of that first MedWatch report,
7 which is dated 4/29/08?

8 A. Prosar.

9 Q. Now, let's look -- hold that open,
10 please.

11 Now, let's look at the
12 supplemental report that's contained
13 within Exhibit 403. And it's dated
14 5/8/2009, correct?

15 A. Yes.

16 Q. And, as you pointed out, this is a
17 second report regarding Karen Bartlett,
18 correct?

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19 A. Yes.
 20 Q. And who created all the
 21 information in this report?
 22 A. Prosar.
 23 Q. As you can see here, at the end of
 24 the first paragraph, they say they
 25 reassessed the case as serious and
 00090
 1 unexpected. Correct?
 2 A. Yes.
 3 Q. And does that mean that in their
 4 evaluation the one or more of the
 5 adverse events being reported was not
 6 set forth in the label?

Witness_ Andria Werynski - Vol. 1.txt: 90:10 - 90:16

THE WITNESS: Yes.
 11 BY MR. JENSEN:
 12 Q. And which adverse events were
 13 those that were unexpected and,
 14 therefore, in Prosar's interpretation
 15 not in the sulindac label?
 16 A. I don't know.

Objection (89:5 to 90:16):
 -402
 -403
 -602
 -801
 -802

Ruling: Sustained as to lines 89:5 through 89:8 and as to lines 89:20 through 90:6. Otherwise overruled.

Witness_ Andria Werynski - Vol. 1.txt: 91:10 - 91:15

Q. Did you have any knowledge of this
 11 reassessment, which clearly this was a
 12 serious unexpected event, in or around
 13 May of 2009?
 14 A. Yes.
 15 Q. And what was that involvement?

Witness_ Andria Werynski - Vol. 1.txt: 91:18 - 91:23

THE WITNESS: I received an
 19 e-mail notification, I believe, that it
 20 was assessed and that they would be
 21 preparing a 15-day alert report, and I
 22 reviewed the 15-day alert report for
 23 completeness and accuracy.

Objection (91:10 to 91:23):
 -402 (report submitted more
 than three years after the
 event)
 -403
 -801
 -802
 -602

Ruling: Sustained as to "which clearly this was a serious unexpected event." Otherwise overruled.

Witness_ Andria Werynski - Vol. 1.txt: 92:17 - 92:24

Q. And the second report that was
 18 submitted of the 15-day report, is it
 19 five pages long?
 20 A. Yes.
 21 Q. And were any of the medical
 22 records following those five pages
 23 submitted to the FDA, to your knowledge?
 24 A. Yes, they all were.

Objection:
 -402
 -403
 -801
 -802
 -602

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 93:25 - 94:12

Q. But you did review the
 00094
 1 supplemental report and all the medical
 2 records attached to it when you
 3 submitted it?
 4 A. Yes.

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5 Q. So you were aware from the very
 6 last page submitted, which is the
 7 discharge summary from Spaulding
 8 Rehabilitation Hospital, that
 9 Mrs. Bartlett was discharged from that
 10 hospital on or about May 19, 2005,
 11 correct?
 12 A. Correct.

Objection:
 -402
 -801
 -802
 -804
 -1003
 -1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 95:25 - 96:5

You knew from the entirety of
 00096

1 these records that Mrs. Bartlett's
 2 events started early February 2005, and
 3 she was now getting discharged from
 4 Spaulding Rehab some four months and 19
 5 days later, correct?

Objection (95:25 to 96:9):
 -402
 -801
 -802
 -804
 -1003
 -1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: Page 96, Line 9

THE WITNESS: Yes.

Witness_ Andria Werynski - Vol. 1.txt: 97:17 - 97:20

You see from her discharge
 18 medications that four are them are
 19 prescribed in relation to her G-tube,
 20 Numbers 1, 2, 4 and 5. Correct?

Objection (97:17 to 98:11):
 -402
 -801
 -802
 -804
 -1003
 -1004

Ruling: Sustained as to lines 97:25
 through 98:11.

Witness_ Andria Werynski - Vol. 1.txt: 97:24 - 98:6

THE WITNESS: Yes.

25 BY MR. JENSEN:

00098

1 Q. Do you know that Ms. Bartlett
 2 needed to continue to be fed through a
 3 G-tube in her stomach for approximately
 4 11 months after this discharge, which
 5 was about four and a half months after
 6 her SJS and TEN started?

Witness_ Andria Werynski - Vol. 1.txt: 98:11 - 98:19

THE WITNESS: No.

12 BY MR. JENSEN:

13 Q. Do you know that a number of Karen
 14 Bartlett's ophthalmologists or eye
 15 doctors have concluded, either through
 16 visual acuity tests or otherwise, that
 17 she has been legally blind in one eye
 18 and often both eyes for most of the last
 19 four years?

Objection (98:13 to 98:24):
 -402
 -403
 -Argumentative
 -Misstates facts
 -Misleading
 -801
 -802

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 98:24 - 99:5

THE WITNESS: No.

25 BY MR. JENSEN:

00099

1 Q. Has anyone from any of the Mutual
 2 companies, URL, AR Holdings, URL Pharma,
 3 any of these companies, ever called

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4 Karen Bartlett to apologize or even to
5 talk to her about how she is doing?

Objection (99:1 to 99:11):
-Argumentative
-402
-403

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 99:10 - 99:11

THE WITNESS: I'm not aware
11 of anyone, no.

Witness_ Andria Werynski - Vol. 1.txt: 100:8 - 100:14

Q. On the supplemental MedWatch
9 report -- if you can flip there, and
10 tell me when you are there, please.
11 A. Okay.
12 Q. Do you see under the Box 2 it has
13 Disability checked?
14 A. Yes.

Objection:
-402
-403
-801
-802
-1003
-1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 101:1 - 101:2

Q. The third paragraph under Box 5.
2 Tell me when you are there, please.

Witness_ Andria Werynski - Vol. 1.txt: 101:21 - 101:24

It reads, on 2/4/08 -- it should
22 read 2/4/05 -- the patient was diagnosed
23 with, I will abbreviate, SJS progressing
24 to TEN. Correct?

Objection (101:1
to 103:6):
-402
-403
-801
-802
-804
-1003
-1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 102:6 - 103:1

THE WITNESS: I could say
7 it's a reasonable assumption that that's
8 a typographical error.
9 BY MR. JENSEN:
10 Q. And I read it correctly, correct?
11 A. That it should be 2005?
12 Q. And the rest of the sentence, that
13 the patient was diagnosed with Stevens-
14 Johnson Syndrome progressing to, I will
15 abbreviate, TEN. Correct?
16 A. Yes.
17 Q. And then it says, the patient was
18 hospitalized for approximately three
19 months for these events, two of which
20 she was in a drug-induced coma.
21 Correct?
22 A. Yes.
23 Q. And it says, the patient developed
24 unspecified scarring some time after the
25 events began, leading to an unspecified
00103
1 permanent disability. Correct?

Witness_ Andria Werynski - Vol. 1.txt: 103:5 - 103:6

THE WITNESS: That's what it
6 says there, yes.

Witness_ Andria Werynski - Vol. 1.txt: 104:9 - 104:13

Bartlett v Mutual

Q. If her ophthalmologists at Harvard
10 have concluded that after nine eye
11 surgeries she will likely never be able
12 to read or work or drive again, do you
13 consider that a permanent disability?

Witness_ Andria Werynski - Vol. 1.txt: 104:22 - 104:23

THE WITNESS: I don't -- I
23 can't classify a significant disability.

Objection (104:9 to
104:23):
-402
-403
-701
-801
-802
-Argumentative
-Speculation

Ruling: Sustained.

Witness_ Andria Werynski - Vol. 1.txt: 106:11 - 106:16

This follow-up report that's being
12 reported to the FDA occurred about six
13 months after the lawsuit was filed,
14 correct? The follow-up visit that was
15 being reported of Ms. Bartlett's
16 treating physician?

Witness_ Andria Werynski - Vol. 1.txt: 106:19 - 107:4

THE WITNESS: Yes. That's
20 correct.

21 BY MR. JENSEN:

22 Q. And what is reported to the FDA is
23 that she had a follow-up visit in July
24 2008, and her medical history included
25 chronic obstructive pulmonary disease,
00107

1 it's abbreviated COPD, and it says that
2 she's legally blind in the right eye,
3 secondary to Stevens-Johnson Syndrome?
4 Correct?

Objection (106:11 to
107:9):
-402
-403
-801
-802
-804
-1003
-1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 107:8 - 107:9

THE WITNESS: That's what her
9 medical records say, yes.

Witness_ Andria Werynski - Vol. 1.txt: 108:21 - 108:25

It's correct that Mutual reported
22 to the FDA in May of 2009 that
23 Ms. Bartlett was legally blind in the
24 right eye secondary to Stevens-Johnson
25 Syndrome? Correct?

Witness_ Andria Werynski - Vol. 1.txt: 109:5 - 109:9

THE WITNESS: Her medical
6 records were submitted to the FDA, yes.

7 BY MR. JENSEN:

8 Q. But I didn't ask you about her
9 medical records.

Objection (108:21 to
109:22):
-402
-403
-801
-802
-804
-1003
-1004

Ruling: Overruled.

Witness_ Andria Werynski - Vol. 1.txt: 109:12 - 109:15

Q. It's correct to state that in May
13 2009, Mutual reported to FDA that
14 Ms. Bartlett was legally blind in her
15 right eye secondary to SJS? Correct?

Bartlett v Mutual

Witness_ Andria Werynski - Vol. 1.txt: 109:18 - 109:22

THE WITNESS: No, I don't see

19 that.

20 BY MR. JENSEN:

21 Q. It's the end of Page 5 of 5.

22 A. Oh. Yes.

Witness_ Andria Werynski - Vol. 1.txt: 109:23 - 110:4

Q. Is blindness a disability, or do

24 you not know?

25 MR. COSGROVE: Objection.

00110

1 Form. Foundation. Argumentative.

2 Assumes facts. Calls for improper

3 expert opinion.

4 THE WITNESS: I don't know.

Objection: -402 -403 -701 -Speculation
--

Ruling: Sustained.

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Witness_ Andrea Werynski - Vol. 1.txt: 1:1 - 1:19

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

2

3
4 KAREN L. BARTLETT, : CASE NO. 08-cv-358-JL
Plaintiff, :
5 :
6 -v.- :
7 :
7 MUTUAL PHARMACEUTICAL :
COMPANY, INC. and UNITED :
8 RESEARCH LABORATORIES, INC., :
Defendants. :
9

10
Friday
11
November 13, 2009
12

13
Oral deposition of ANDREA WERYNSKI, held at
14
the Law Offices of Segal, McCambridge, Singer & Mahoney,
15
LTD, United Plaza, 30 South 17th Street, Suite 1700,
16
Philadelphia, Pennsylvania, commencing at 10:08 a.m. on
17
the above date, before Christine M. Aguado, a Professional
18
Court Reporter and Notary Public in the Commonwealth of
19
Pennsylvania.

Witness_ Andrea Werynski - Vol. 1.txt: 4:21 - 4:22

Q. Please state your name for the record.

22 A. Andrea Werynski.

Witness_ Andrea Werynski - Vol. 1.txt: 4:23 - 5:8

And we've met at your prior
24 deposition, correct?

25 A. Yes.

00005

1 Q. Did you read your prior deposition after you gave
2 that testimony that day?

3 A. Yes.

4 Q. Did you make any changes to your testimony?

5 A. No.

6 Q. Is it fair to assume that the reason that you did
7 not make any changes to your testimony is that you did not
8 find any errors in it?

Objection (4:23 to 4:25):
-402

Ruling: Overruled.

Objection (5:1 to 5:8):
-Improper bolstering
-402

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 5:10 - 5:15

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THE WITNESS: Yes.

11 BY MR. JENSEN:

12 Q. And do you understand that one of the reasons
13 we're here today is that you've been designated as
14 corporate representative on behalf of one or more
15 corporations to provide testimony on one or more topics?

Witness_ Andrea Werynski - Vol. 1.txt: Page 5, Line 18

Objection (5:12 to 5:18):
-402
-Vague

Ruling: Overruled.

THE WITNESS: Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 6:22 - 7:1

Q. How many times, to your knowledge, either before
23 you arrived at Mutual, because you might have knowledge of
24 that, or since you arrived at Mutual has Mutual or AR
25 Holdings or URL or one of its other affiliated companies
00007
1 ever filed a citizen's petition for any reason?

Witness_ Andrea Werynski - Vol. 1.txt: 7:5 - 7:6

THE WITNESS: I'm aware of them. I have
6 no idea how many.

Objection (6:23 to
8:16):
-402 (events after
12/04), (NDA)
-403
-407
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 7:9 - 7:10

So please now

10 tell me how many you have knowledge of.

Witness_ Andrea Werynski - Vol. 1.txt: 7:14 - 8:16

THE WITNESS: Approximately three.

15 BY MR. JENSEN:

16 Q. And please identify the three that you're aware
17 of.

18 A. Colcris, for a product Colcris, for a product
19 Skelaxin -- Metaxalone, and I think that's it.

20 Q. Okay. And you said approximately three, but I
21 think you just said two drugs. Was there three in
22 relation to these drugs that you have knowledge of?

23 A. I don't know. No, I really don't know.

24 Q. And Skelaxin is the brand name and Metaxalone is
25 the chemical?

00008

1 A. Yes.

2 Q. Colcris is the brand name?

3 A. Yes.

4 Q. What is the chemical?

5 A. Colchicine.

6 Q. Can you spell that?

7 A. C-O-L-C-H-I-C-I-N-E.

8 Q. And Mutual holds the NDA or ANDA for Colcris?

9 A. NDA.

10 Q. And Mutual holds the NDA or ANDA for Skelaxin?

11 A. Neither.

12 Q. What does it hold?

13 A. Nothing.

14 Q. Did it ever hold one of them, to your knowledge,
15 for Skelaxin?

16 A. No.

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Witness_ Andrea Werynski - Vol. 1.txt: 13:18 - 13:20

Q. Did Mutual attempt to enhance safety information
19 in its Qualaquin Physicians' Desk Reference or package
20 insert label?

Objection (13:18 to
14:18):
-402 (NDA products)
-403
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 13:25 - 14:9

THE WITNESS: When?

00014

1 BY MR. JENSEN:

2 Q. Since August 2005.

3 A. Yes.

4 Q. What did it do in that regard?

5 A. I'm only aware of one specific instance, and it
6 was to update information pertaining to thrombocytopenia.

7 Q. And what did Mutual do to update information
8 regarding thrombocytopenia in its NDA product Qualaquin
9 label?

Witness_ Andrea Werynski - Vol. 1.txt: 14:16 - 14:18

THE WITNESS: I don't know the specific

17 details. I know they increased the strength

18 warning for it.

Witness_ Andrea Werynski - Vol. 1.txt: 15:17 - 15:19

Q. What was Prosar's role, if any, in the changes of
18 the Qualaquin label to add additional risk information
19 regarding thrombocytopenia?

Objection (15:17 to
15:24):
-402 (time)
-403
-407 (Prosar engaged
after Rx date 12/04)
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: Page 15, Line 24

THE WITNESS: I did not have a role.

Witness_ Andrea Werynski - Vol. 1.txt: 21:11 - 21:15

Q. How often does Prosar survey the medical
12 literature for Mutual's ANDA drugs?

13 A. They have their own standard operating procedures
14 that specifies how often they do that. It's -- I believe
15 it's done weekly.

Objection:
-402 (time)
-403
-407 (Prosar engaged
after Rx date 12/04)
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 23:17 - 23:24

Q. When did Prosar start doing medical literature
18 surveillance for Sulindac?

19 A. I don't have a specific date, but I believe they
20 began surveying the literature for all of our products in
21 association with the Qualaquin NDA approval.

22 Q. Better than associated, do you believe it started
23 happening at the same time the Qualaquin NDA was approved;
24 is that correct?

Objection (23:17 to
24:23):
-402 (NDA products)
-403
-407 (Prosar and
Qualaquin and
literature survey after
12/04)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 24:2 - 24:9

THE WITNESS: Around the same time, yes.

3 BY MR. JENSEN:

4 Q. And you estimated for me before that the

5 Qualaquin NDA was in August 2005; is that correct?

6 A. Yes.

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7 Q. If that estimation is accurate, is that when,
8 August 2005, you believe that Prosar starting doing
9 medical literature surveillance for Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 24:13 - 24:18

THE WITNESS: Yes.

14 BY MR. JENSEN:

15 Q. And if that August 2005 estimation is correct, is
16 that also the first month and year that Prosar started
17 doing medical literature surveillance for all of Mutual's
18 approximate 100 ANDAs?

Witness_ Andrea Werynski - Vol. 1.txt: 24:22 - 24:23

THE WITNESS: It's all an approximation,
23 but yes.

Witness_ Andrea Werynski - Vol. 1.txt: 30:10 - 30:16

Tell me, when Prosar identifies a

11 15-day report, what happens?

12 A. When they identify a 15-day report, they prepare
13 the Med Watch. They send it to Mutual where it's reviewed
14 by either Dr. Davis or Dr. Wason and myself, and then when
15 we let Prosar know if we approve it, then Prosar submits
16 it.

Objection:

-402
-403 (Prosar engaged
for literature reviews
after 12/04)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 31:11 - 31:16

Tell me, Prosar identifies 15-day

12 alert reports. Prosar does the substance and analysis of
13 whether or not they should be reported yet to the FDA.

14 Mutual solely reviews the same for completeness and Mutual
15 does not review the same for reportability. If and when
16 Mutual says it's complete, Prosar submits it to the FDA?

Objection (31:11 to
31:21):

-402
-403
-407 (post-dates 12/04
Rx)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: Page 31, Line 21

THE WITNESS: Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 32:17 - 32:22

Q. Hence, what you agreed to as the relationship and
18 how it works for a 15-day alert of reports as between
19 Prosar and Mutual has been true since approximately the
20 fall of 2008 for all of Mutual's ANDAs and/or NDAs,
21 correct?

22 A. Yes.

Objection:

-402
-403
-407 (post-dates 12/04
Rx)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 33:3 - 33:5

Q. Between August 2005 and the fall of 2008, tell me

4 how it worked then in that time period for 15-day alert
5 reports.

Objection (33:3 to
33:23):

-402
-403
-407 (post-dates 12/04
Rx)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 33:8 - 33:19

THE WITNESS: It worked the same, except

9 when the Med Watch was sent to Mutual and it was
10 reviewed and considered accurate and complete,
11 Mutual submitted it. They actually put it in the

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12 mail rather than Prosar putting it in the mail.
 13 BY MR. JENSEN:
 14 Q. In that time period, approximately three years
 15 between August 2005 and sometime in the fall of 2008, was
 16 it still true that Mutual was not doing an analysis
 17 regarding reportability? It was only doing a review of
 18 completeness. Hence, Prosar was doing the analysis and
 19 reportability.

Witness_ Andrea Werynski - Vol. 1.txt: Page 33, Line 23

THE WITNESS: Yes, that is correct.

Witness_ Andrea Werynski - Vol. 1.txt: 34:23 - 35:1

What are the requirements for an ANDA
 24 filer of an annual report in terms of in stating the
 25 report what information might affect the safety profile of
 00035

1 the product or its label?

Witness_ Andrea Werynski - Vol. 1.txt: 35:7 - 35:12

THE WITNESS: There is no such
 8 stipulation in an annual report.

9 BY MR. JENSEN:

10 Q. Is there any requirement in an annual report for
 11 an ANDA holder to comment on information that may affect
 12 the safety profile of the product?

Witness_ Andrea Werynski - Vol. 1.txt: 35:18 - 35:21

THE WITNESS: Are you talking about an
 19 annual report or a periodic report?

20 MR. JENSEN: Annual report.

21 THE WITNESS: Not that I'm aware of.

Witness_ Andrea Werynski - Vol. 1.txt: 37:2 - 37:6

Q. Is the following a correct statement? Prosar has
 3 not been hired by Mutual or any of its related entities to
 4 evaluate whether or not Mutual or its related entity
 5 labels are in conformity or not with the requirements of
 6 the code of federal regulations.

Witness_ Andrea Werynski - Vol. 1.txt: 37:11 - 37:13

THE WITNESS: Prosar was not hired to
 12 evaluate Mutual's labeling for any of their
 13 products.

Witness_ Andrea Werynski - Vol. 1.txt: 42:18 - 42:23

And 430, as you
 19 can see, is a citizen's petition signed by Mr. Dennery on
 20 March 6th, 2001. Do you see that?

21 A. Yes.

22 Q. And it involves the product of Skelaxin, correct?

23 A. Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 43:9 - 43:12

Objection (34:23 to
 35:21):
 -402
 -403 (no evidence of
 such a requirement)

Ruling: Sustained.

Objection (37:2 to
 37:13):
 -402
 -403
 -407 (Prosar engaged
 after 12/04)

Ruling: Sustained.

Objection:
 -402 (not product at
 issue; NDA product)
 -403
 -602 (see line 42:21)

Ruling: Sustained.

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Q. I understand that you were not with Mutual in 2001, is it correct that you've come to learn that Mutual has filed a number of citizens' petitions regarding the product Skelaxin?

Witness_ Andrea Werynski - Vol. 1.txt: Page 43, Line 15

THE WITNESS: Yes.

Objection (43:9 to 43:15):
-402 (not product at issue; NDA product)
-403
-602 (see line 42:21)

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 44:9 - 44:12

Q. Do you understand or do you not that Mutual's citizens' petitions in part might affect the labeling of Skelaxin that Mutual has requested that the FDA take action regarding the labeling of Skelaxin, correct?

Objection (44:9 to 44:22):
-402 (not product at issue; NDA product)
-403
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 44:21 - 44:25

A. I don't know what the citizen's petition is for. I haven't read it.
Q. Do you recognize Exhibit-431 to be Mutual's petition for stay at action filed through Mutual's attorneys in April 2004 regarding the product Skelaxin?

Witness_ Andrea Werynski - Vol. 1.txt: 45:4 - 45:11

THE WITNESS: I don't know. It says on behalf of Mutual, but I don't recognize it as something I've seen.

BY MR. JENSEN:

Q. Do you recognize Exhibit-432 to be Mutual's supplemental submission regarding Skelaxin in February 2005 submitted through its other attorneys, Zuckerman Spaeder?

Witness_ Andrea Werynski - Vol. 1.txt: 45:16 - 45:21

THE WITNESS: It says Mutual on it.

BY MR. JENSEN:

Q. And does it also say, starting on the third line, both petitions concern the significance of the labeling that King has proposed regarding the possible food effects of King's drug Skelaxin?

Objection (44:23 to 45:6):
-402 (not product at issue; NDA product)
-403
-602

Ruling: Sustained.

Objection (45:8 to 45:25):
-402 (not product at issue; NDA product)
-403
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 45:24 - 46:4

THE WITNESS: Yes, the document says that.

00046

BY MR. JENSEN:

Q. Do you recognize Exhibit-433 to be another citizen's petition by Mutual this time in May 2009 regarding Skelaxin?

Witness_ Andrea Werynski - Vol. 1.txt: 46:21 - 46:25

THE WITNESS: It says May 13th, 2009, filed by Mutual.

BY MR. JENSEN:

Q. Do you recognize that to be Robert Dennerly's signature on Page 8?

Objection (46:2 to 47:3):
-402 (not product at issue; NDA product)
-403
-602
-407 (post-dates event)

Ruling: Sustained (through line 48:24).

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Witness_ Andrea Werynski - Vol. 1.txt: Page 47, Line 3

THE WITNESS: Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 47:13 - 47:16

Q. Do you see that the first item, that through the
14 citizen's petition that Mutual this year has requested
15 that the FDA declare Skelaxin misbranded unless King
16 updates its labeling?

Witness_ Andrea Werynski - Vol. 1.txt: 47:21 - 47:25

THE WITNESS: Yes, that's what it says.

22 BY MR. JENSEN:

23 Q. Were you aware at any time in 2009 of Mutual's
24 intent or actual pursuit of this action through this
25 citizen's petition?

Witness_ Andrea Werynski - Vol. 1.txt: 48:5 - 48:10

THE WITNESS: I was aware that Mutual

6 filed a citizen's petition stating or suggesting
7 that Skelaxin should be a delayed-release
8 product.

9 BY MR. JENSEN:

10 Q. And that is the petition, Exhibit-433, correct?

Witness_ Andrea Werynski - Vol. 1.txt: 48:14 - 48:19

THE WITNESS: Yes.

15 BY MR. JENSEN:

16 Q. And what you referred to as the second item of
17 relief that Mutual seeks in this citizen's petition which
18 is that King be required to update the dosage form listing
19 to have it read delayed release, correct?

Witness_ Andrea Werynski - Vol. 1.txt: 48:24 - 49:4

THE WITNESS: Yes.

25 BY MR. JENSEN:

00049

1 Q. And do you understand these to be the same
2 efforts in part that Mutual was involved in Exhibit-430
3 back in 2001 and through two different law firms in 2004,
4 Exhibit-431, and in 2005, Exhibit-432?

Witness_ Andrea Werynski - Vol. 1.txt: 49:10 - 49:16

THE WITNESS: I don't know other than

11 the product name in which these citizens'
12 petitions are related.

13 BY MR. JENSEN:

14 Q. And Exhibit-431 shows us that the law firm named
15 Heller Ehrman represented Mutual at that time in April of
16 2004, correct?

Witness_ Andrea Werynski - Vol. 1.txt: 49:19 - 49:24

THE WITNESS: Yes.

20 BY MR. JENSEN:

21 Q. And Exhibit-432 shows us that a law firm called

Objection (49:1 to
49:12):
-402
-403
-602

Ruling: Sustained.

Objection (49:14 to
49:24):
-402
-403
-602

Ruling: Sustained.

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22 Zuckerman Spaeder represented Mutual at that time in
23 February 2005, correct?

24 A. Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 51:12 - 51:15

Q. Is it correct that the fifth item of relief that
13 Mutual in May 2009 citizen's petition was to require a
14 different drug company; namely, King Pharmaceutical, to
15 perform a pharmacokinetic study?

Objection (51:12 to
51:21):
-402
-403
-407
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 51:20 - 51:21

THE WITNESS: The document says required
21 King to perform a pharmacokinetic study.

Witness_ Andrea Werynski - Vol. 1.txt: 52:24 - 52:25

Q. When did Mutual file a citizen's petition for
25 Colcrlys?

Objection (52:24 to
53:8):
-402
-403
-407
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 53:3 - 53:8

THE WITNESS: I don't know when Mutual
4 filed their citizen's petition for Colcrlys.

5 BY MR. JENSEN:

6 Q. Do you know what year or an approximation of what
7 year?

8 A. Approximately 2008, 2009.

Witness_ Andrea Werynski - Vol. 1.txt: 53:18 - 53:20

does that signature
19 on Page 5 also appear to be, in fact, Mr. Dennery's
20 signature?

Objection:
-402 (NDA product and
not product at issue;
time)
-403

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 54:1 - 54:2

THE WITNESS: Yes, that appears to be
2 his signature.

Witness_ Andrea Werynski - Vol. 1.txt: 54:4 - 54:9

Q. Have you ever heard of a Dr. Daniel Azernof?

5 A. No.

6 Q. To your knowledge, how many times has Mutual
7 hired a doctor like Dr. Azernof, not in relation to
8 litigation, but actually in relation to Mutual's efforts
9 to get a label changed like the Skelaxin label?

Objection (54:4 to
54:15):
-402
-403
-602
-Foundation

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 54:14 - 54:15

THE WITNESS: I don't know how often
15 they hire doctors.

Witness_ Andrea Werynski - Vol. 1.txt: 55:4 - 55:8

Q. How many times has Mutual, to your knowledge,
5 ever hired a medical expert or consultant to aid Mutual in
6 its efforts to change a label regarding safety, in whole
7 or in part, on one of its drugs or a drug that is not a
8 Mutual drug, but that Mutual is interested in pursuing?

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Objection (55:4 to 55:25):
-402
-403
-407
-Vague

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 55:14 - 55:20

THE WITNESS: I'm only aware of one
15 time.

16 BY MR. JENSEN:

17 Q. What time is that?

18 A. This year, 2009.

19 Q. What was the drug and what was Mutual trying to
20 accomplish by hiring them?

Witness_ Andrea Werynski - Vol. 1.txt: Page 55, Line 25

THE WITNESS: It was Qualaquin.

Witness_ Andrea Werynski - Vol. 1.txt: 57:17 - 58:11

Q. The first page of 403, whose signature is that on
18 the bottom?

19 A. Beatrice Rivera.

20 Q. And do you recognize some or all of the
21 handwriting on it and do you know who is the author of any
22 of it?

23 A. I recognize some of it, yes.

24 Q. Is it yours?

25 A. Yes.

00058

1 Q. Now, identify the date entries that are your
2 writing.

3 A. May 1st, 2009.

4 Q. So above your note on 2/11/08, it says case is
5 listed as expected and serious. No investigation
6 required, correct?

7 A. That is what it says, yes.

8 Q. Do you know who wrote that?

9 A. Yes.

10 Q. Who?

11 A. Beatrice Rivera.

Objection:
-402
-403
-407
-Vague, ambiguous
with regard to what
question relates to best
evidence

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 59:21 - 59:25

Q. Is what Pages 2 and 3 on Exhibit-403 are in part
22 is a list of terms that the person who reviewed Karen
23 Bartlett's complaint found to be in the label, and, in
24 other terms, in association with her case, the reviewer
25 had found not to be in the Sulindac label?

Witness_ Andrea Werynski - Vol. 1.txt: 60:3 - 60:18

THE WITNESS: These are all terms pulled

4 from the medical records and their assessment of
5 them, yes.

6 BY MR. JENSEN:

7 Q. Is it correct that your understanding is the
8 reviewer pulled these terms from Karen Bartlett's medical
9 records and if the reviewer found those terms in the
10 Sulindac label, then they identified it as expected.
11 We'll stop there.

12 A. I don't know how they assess expectedness and
13 unexpectedness, but the general concept is if it's in the
14 label, it's expected.

15 Q. Okay. Conversely, is it your understanding that

Objection (59:21 to 61:8):
-402
-403
-801
-802
-1002

Ruling: Sustained. References to
Prosar's work and conclusions are
unfairly prejudicial (Rule 403).

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16 if the reviewer did not find the term on the Sulindac
17 label, they characterize it on these two pages as an
18 unexpected event?

Witness_ Andrea Werynski - Vol. 1.txt: 60:21 - 61:2

THE WITNESS: That is my general
22 understanding of the process, yes.

23 BY MR. JENSEN:

24 Q. And will you please count and agree with me that
25 based upon this review that was done by Prosar, that
00061

1 reviewer found 14 different conditions in Karen Bartlett's
2 medical records which were not in the Sulindac label?

Witness_ Andrea Werynski - Vol. 1.txt: 61:5 - 61:8

THE WITNESS: Well, if you look at the
6 original one these weren't in there. These were
7 all associated or because of the original adverse
8 event.

Witness_ Andrea Werynski - Vol. 1.txt: 61:11 - 61:22

So
12 you're saying that you think these all flow from TEN or
13 SJS?

14 A. Yes.

15 Q. That is not your medical opinion? That's your
16 understanding of what you think happened?

17 A. That's my understanding of how the case
18 progressed because originally, the AE terms were SJS and
19 TEN.

20 Q. Right. And this information, as you noted, was
21 based upon new information received which was specifically
22 the medical records, correct?

Objection (61:11 to
61:25):
-402
-403
-602
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 61:25 - 62:7

THE WITNESS: Yes, that's correct.
00062

1 BY MR. JENSEN:

2 Q. Now, do you agree with me that based upon this
3 new information, i.e., Karen Bartlett's medical records,
4 that the reviewer at Prosar identified 14 conditions in
5 Karen Bartlett's medical records that they listed as
6 unexpected. To your knowledge, that means that they were
7 not in the Sulindac label, correct?

Objection (62:2 to
63:7):
-402
-403
-407
-801
-802
-602
-702 (Prosar not
medical expert)
-Rule 26a(2) (Prosar
not disclosed)
-1002

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 62:12 - 63:1

THE WITNESS: There are 14 terms that
13 are listed as unexpected.

14 BY MR. JENSEN:

15 Q. And the 14 terms listed as unexpected that are,
16 therefore, based upon Prosar's review, not on the Sulindac
17 label, are: One, scarring; two, corneal defects; three,
18 vancomycin resistant enterococcal infection; four, acute
19 respiratory distress syndrome; five, DVT or deep vein
20 thrombosis; six, an acronym, SIADH; seven, lobar
21 pneumonia; eight, staphylococcal infection; nine, chronic
22 obstructive pulmonary disease; ten, blindness in the right

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23 eye or blindness unilateral; eleven, esophageal
24 restriction; twelve, unilateral complete paralysis in the
25 vocal cords; thirteen, dehydration; fourteen, urinary
00063
1 tract infection.

Witness_ Andrea Werynski - Vol. 1.txt: 63:6 - 63:11

THE WITNESS: That is what the document

7 says, yes.

8 BY MR. JENSEN:

9 Q. Do you know who at Prosar conducted this
10 review to find those 14 items in Karen Bartlett's medical
11 records which are not on the Sulindac label?

Objection (63:9 to
63:24):
-402
-407
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 63:17 - 63:24

THE WITNESS: I don't know who at Prosar
18 performed the assessment.

19 BY MR. JENSEN:

20 Q. Did you ever have any conversations at all with
21 anybody regarding the follow up of Karen Bartlett's
22 analysis?

23 A. I e-mailed them medical records and they notified
24 us that it was ungraded to serious unexpected.

Witness_ Andrea Werynski - Vol. 1.txt: 64:4 - 64:15

Q. Does 434 appear to you to be a copy of the
5 Sulindac label as of February 2002?

6 A. Yes.

7 Q. And that's Mutual's Sulindac label, correct?

8 A. Yes.

9 Q. Back at Exhibit-403 -- if you would flip to the
10 Med Watch report, the follow up one. It's five-pages
11 long. Tell me when you're there, please.

12 A. (Witness complies.)

13 Q. And have you seen this five-page follow-up report
14 regarding Ms. Bartlett's medical records from before?

15 A. Yes.

Objection (64:9 to
64:24):
-402
-403
-407
-602
-Foundation

Ruling: Sustained as to the references
to Prosar's work and its conclusions
(Rule 403). Otherwise overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 64:18 - 64:24

But what I'm going to do with you now,

19 Ms. Werynski, is identify some additional things that are
20 identified here in Mutual/Prosar's follow-up report and
21 ask you whether they're in the label that are in addition
22 to the 14 things that Prosar concluded that were not in
23 the label. Do you understand what I'm asking you to do?
24 A. No.

Witness_ Andrea Werynski - Vol. 1.txt: 67:14 - 67:17

Q. Please confirm for me that there is no other
15 statement in the label that identifies that as a result of
16 taking Sulindac, there might be a coma or a drug-induced
17 coma.

Objection (67:14 to
68:11):
-Improper publishing
-Argumentative
-402
-407
-602
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 67:20 - 68:1

THE WITNESS: No. I don't know see anywhere
21 where it says drug-induced coma.

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22 BY MR. JENSEN:

23 Q. And do you also agree that there is nothing in
24 the label that informs someone that they might have a coma
25 as a result of taking Sulindac on the Mutual Sulindac
00068
1 label?

Witness_ Andrea Werynski - Vol. 1.txt: 68:6 - 68:11

THE WITNESS: I don't see coma in the
7 insert, no.

8 BY MR. JENSEN:

9 Q. When you say insert, you're referring to the
10 label, correct?
11 A. Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 70:23 - 71:7

What I'm going to do,

24 Ms. Werynski, is for each of these matters I've identified
25 -- I'll identify them again for clarity of the question.
00071

1 I'll ask you to tell us whether or not that medical
2 condition which is in Mutual's own follow-up report to the
3 FDA, which is not an unexpected event in its listing on
4 Pages 2 and 3, whether or not they're in the Sulindac
5 label.

6 Do you understand what I'm going to ask?
7 A. Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 71:13 - 71:16

Starting with ventilator, which is
14 characterized as vent dependence. Is there anything in
15 the Sulindac label that advises that someone might go on a
16 ventilator if they take Mutual's Sulindac product?

Objection (70:23 to
73:7):

-Argumentative
-Foundation
-402
-403
-602
-702
-801
-802
-1002

Ruling: Sustained as to "which is not an
unexpected event in its listing on Pages
2 and 3." Otherwise overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 71:23 - 72:2

THE WITNESS: I do not see vent
24 dependence in the insert.

25 BY MR. JENSEN:
00072

1 Q. Or maybe it's under ventilator or breathing tube,
2 correct?

Witness_ Andrea Werynski - Vol. 1.txt: Page 72, Line 6

THE WITNESS: No, I do not see that.

Witness_ Andrea Werynski - Vol. 1.txt: 72:13 - 72:16

Q. Do you see anything in the Sulindac label
14 which advises that someone might need to get trached or go
15 on a tracheostomy as Mutual found Karen Bartlett needing
16 to do after taking Mutual's Sulindac product?

Witness_ Andrea Werynski - Vol. 1.txt: 72:18 - 73:2

THE WITNESS: I do not see the term
19 tracheostomy in the Sulindac insert.

20 BY MR. JENSEN:

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21 Q. And again, the insert refers to the Sulindac
22 label, correct?
23 A. Yes.
24 Q. Do you see anything in Mutual's insert or
25 Sulindac label that advises that someone might need one or
00073
1 multiple bronchoscopies if they take Sulindac, Mutual's
2 product?

Witness_ Andrea Werynski - Vol. 1.txt: 73:6 - 73:7

THE WITNESS: I don't see bronchoscopy
7 in the label.

Witness_ Andrea Werynski - Vol. 1.txt: 74:15 - 74:18

both her medical records and what was
16 lifted from them in Mutual's report to the FDA, you
17 reported that Ms. Bartlett had five bronchoscopies,
18 correct?

Witness_ Andrea Werynski - Vol. 1.txt: 74:21 - 75:4

THE WITNESS: Yes.

22 BY MR. JENSEN:

23 Q. Next is the recordation and the report to the FDA
24 was that Ms. Bartlett needed Morphine and Versed, a pain
25 medication, a conscious sedation medication. Is there
00075

1 anything in the Mutual Sulindac label that says they might
2 need one or both of those medications to treat conditions,
3 illnesses, or diseases that might result from the Sulindac
4 product that was being taken?

Objection (74:15 to
75:4):

-Argumentative
-Foundation

-402
-403
-602
-702
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 75:12 - 75:19

Q. It's not in there, correct?

13 A. No.

14 Q. And is there any information in the Sulindac
15 label that alerts someone that they might need Methadone
16 for pain, Ativan for agitation based upon the conditions,
17 illnesses, or diseases that they might get from taking
18 Sulindac product as was reported to the FDA that
19 Ms. Bartlett had?

Witness_ Andrea Werynski - Vol. 1.txt: 76:3 - 76:14

THE WITNESS: No. Methadone and Ativan

4 is not in the insert.

5 BY MR. JENSEN:

6 Q. And do you see where Mutual reported to the FDA
7 that Ms. Bartlett needed packed white blood cells,
8 Albumin, and Crystalloid?

9 A. Yes.

10 Q. Are any of those three blood products or any
11 blood product identified in the Sulindac label that
12 someone might need blood transfusions of all of these
13 three or any type based upon conditions or diseases they
14 might get if they take the Sulindac product?

Objection (75:12 to
76:17):

-Argumentative
-Foundation

-402
-403
-602
-702
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 76:16 - 76:17

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THE WITNESS: I don't see those three
17 blood products in the product insert.

Witness_ Andrea Werynski - Vol. 1.txt: 76:23 - 77:1

Q. Do you see where Mutual reported to the FDA that
24 Ms. Bartlett needed intermittent presser support and that
25 she had hypoalbuminemia and anemia?
00077

1 A. Yes, I see that.

Objection:
-Argumentative
-Foundation
-402
-403
-602
-702
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 77:16 - 77:19

Q. Do you agree that there's nothing in the label
17 that advises someone that takes Sulindac product that they
18 might be on presser support or they might get
19 hypoalbuminemia as a result of the taking Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 78:1 - 78:5

THE WITNESS: I don't see
2 hypoalbuminemia in the insert.
3 BY MR. JENSEN:
4 Q. And do you also agree that you don't see anything
5 about presser support in the label?

Witness_ Andrea Werynski - Vol. 1.txt: 78:8 - 78:14

THE WITNESS: I don't see that in there.
9 BY MR. JENSEN:
10 Q. On Page 3, do you see where Mutual reported to
11 the FDA that Ms. Bartlett had oral airway sloughing and
12 described oral airway sloughing as having thick, bloody
13 secretions?
14 A. Yes, I see that.

Objection (77:16 to
90:12):
-Argumentative
-Foundation
-402
-403
-602
-702
-801
-802
-1002

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 78:18 - 78:21

Q. Do you agree that there's nothing in Mutual's
19 Sulindac label which alerts a reader that a person taking
20 Sulindac might get oral airway sloughing with or without
21 thick, bloody secretions?

Witness_ Andrea Werynski - Vol. 1.txt: 79:1 - 79:6

THE WITNESS: I do not see the term oral
2 airway sloughing or thick, bloody secretions in
3 the insert.
4 BY MR. JENSEN:
5 Q. Do you see where Mutual advises the FDA that
6 Ms. Bartlett needed a chest tube?

Witness_ Andrea Werynski - Vol. 1.txt: 79:9 - 79:15

THE WITNESS: Yes.
10 BY MR. JENSEN:
11 Q. Do you agree that there is nothing in Mutual's
12 Sulindac label which alerts the reader that someone taking
13 Mutual's Sulindac product might need a chest tube for the
14 diseases and conditions that result from taking Mutual's
15 Sulindac product?

Bartlett v Mutual

Witness_ Andrea Werynski - Vol. 1.txt: 79:22 - 80:8

THE WITNESS: I do not see chest tube in
23 the insert.

24 BY MR. JENSEN:

25 Q. Do you see where Mutual advised the FDA that
00080

1 Karen Bartlett had what is called a passy-muir valve?

2 A. Yes.

3 Q. Do you agree that there is nothing in the
4 Sulindac label which alerts its reader to the fact that
5 someone might need a valve, any type of valve, to be
6 implanted in their throat or otherwise to treat any
7 conditions or diseases that will result from taking
8 Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 80:15 - 80:25

THE WITNESS: No, that term is not in
16 the insert.

17 BY MR. JENSEN:

18 Q. Next paragraph was where Mutual informed the FDA
19 in part that Karen Bartlett had to be on total parenteral
20 nutrition, which is also known as tube feeding, correct?

21 A. Yes.

22 Q. Do you agree that nothing in Mutual's Sulindac
23 label which alerts its readers that someone might have to
24 be tube fed for the diseases or conditions as a result of
25 taking Mutual's Sulindac product?

Witness_ Andrea Werynski - Vol. 1.txt: 81:10 - 81:23

THE WITNESS: TPN? I do not see that in
11 the label.

12 BY MR. JENSEN:

13 Q. Or a tube feed, correct?

14 A. Correct.

15 Q. Do you see the next paragraph where Mutual
16 advised the FDA that Karen Bartlett needed a Foley
17 catheter?

18 A. Yes.

19 Q. Do you agree that there is nothing in Sulindac's
20 label that advises someone that they might need to have a
21 catheter inserted in their genital area where Foley
22 catheters are inserted to treat any diseases or conditions
23 that result from Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 82:5 - 82:15

THE WITNESS: No, I do not see that.

6 BY MR. JENSEN:

7 Q. Do you agree that in two paragraphs down that
8 Mutual advised the FDA that Karen Bartlett needed
9 a Fragmin, a blood thinner to treat a DVT?

10 A. Yes.

11 Q. Do you agree that there is nothing in the Mutual
12 Sulindac label which advises or alerts its reader that
13 someone might need either Fragmin, one blood thinner, or
14 Coumadin, another blood thinner, to treat conditions or
15 diseases which can result from taking Sulindac's product?

Witness_ Andrea Werynski - Vol. 1.txt: 82:22 - 83:7

Bartlett v Mutual

THE WITNESS: I do not see Fragmin or

23 Coumadin in the insert.

24 BY MR. JENSEN:

25 Q. Do you agree that on the next page Mutual advised
00083

1 the FDA that Karen Bartlett had a 60 percent open on

2 admission with sloughing referring to her skin?

3 A. Yes.

4 Q. Do you see anywhere in the Sulindac label that

5 alerts the reader that someone might have 60 percent of

6 their skin fall off if they take Mutual Sulindac's

7 product?

Witness_ Andrea Werynski - Vol. 1.txt: 83:16 - 84:4

THE WITNESS: I don't see 60 percent

17 open on admission with Sulfane in the insert

18 label, but I do see hypersensitivity and severe

19 skin reactions in the insert.

20 BY MR. JENSEN:

21 Q. Do you see in that same paragraph where they

22 identify three different treatments that were used on

23 Karen's skin, mainly Aquacel, Acticoat, and Mepetel?

24 A. Yes.

25 Q. And do you agree that there's nothing in Mutual's

00084

1 Sulindac label that tells or alerts its readers that they

2 might need three different types of skin dressings to

3 treat their skin when it's infected or falling off or

4 sloughing as a result of taking Mutual's Sulindac product?

Witness_ Andrea Werynski - Vol. 1.txt: 84:12 - 84:14

THE WITNESS: I don't see reference to

13 Aquacel, Acticoat, or Mepetel in the Sulindac

14 insert.

Witness_ Andrea Werynski - Vol. 1.txt: 84:24 - 85:3

Q. Sure. Do you also know that Karen Bartlett was

25 treated with pig skin which sometimes doctors refer to it

00085

1 as pig skin, like Dr. Schultz who put it on her?

2 Sometimes they refer to it as a xenograph.

3 A. No.

Witness_ Andrea Werynski - Vol. 1.txt: 85:10 - 85:14

Q. Do you agree that there's nothing in Mutual's

11 Sulindac label which alerts its reader that they might

12 need to have pig skin applied or medically xenographed,

13 which is the same thing as pig skin, on their body as a

14 result of taking Mutual's Sulindac product?

Witness_ Andrea Werynski - Vol. 1.txt: 85:21 - 86:13

THE WITNESS: No, I do not see pig skin

22 in the insert.

23 BY MR. JENSEN:

24 Q. Or a xenograph, correct?

25 A. Or a xenograph, no.

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00086

1 Q. The next paragraph pertains to GYN, and it says
2 her vulva was erythematous and desquamated. Her labia was
3 erythematous, but well-demarcated without adhesions. Do
4 you see that?

5 A. I do see that, yes.

6 Q. And that's what Mutual reported to the FDA from
7 Karen's medical records, correct?

8 A. Yes.

9 Q. Do you agree that there's nothing in the Mutual
10 Sulindac label which alerts its readers that they might
11 have vaginal sequelae or vaginal complications, including
12 erythematous vulva as a result of taking Mutual's Sulindac
13 product?

Witness_ Andrea Werynski - Vol. 1.txt: 86:20 - 86:23

THE WITNESS: Skin reaction, severe skin

21 reaction is in the insert, but vulva with
22 erythematous and desquamated labia with
23 erythematous is not in the insert.

Witness_ Andrea Werynski - Vol. 1.txt: 87:3 - 87:7

Q. I'm representing to you, Ms. Werynski, that the
4 pages handed to you was Dr. Colleen Ryan's medical records
5 from the Harvard/Mass General Burn Unit. Can you read me
6 that portion I highlighted there from Dr. Colleen Ryan's
7 medical records, please?

Witness_ Andrea Werynski - Vol. 1.txt: 87:10 - 87:16

THE WITNESS: She has vaginal adhesion.

11 BY MR. JENSEN:

12 Q. Do you agree with me that there is nothing in
13 Mutual Sulindac label which alerts its readers that
14 someone might get vaginal adhesion as Dr. Ryan documented
15 that Ms. Bartlett had from taking Mutual's Sulindac
16 product?

Witness_ Andrea Werynski - Vol. 1.txt: 87:25 - 88:12

THE WITNESS: I don't see vaginal

00088

1 adhesions in the product insert.

2 BY MR. JENSEN:

3 Q. Okay. And the product insert is the same thing
4 as the label that we're talking about, right?

5 A. Yes.

6 Q. Do you see on that same page, the last paragraph,
7 where Mutual reported to the FDA that Karen had dysphagia?

8 A. I see that, yes.

9 Q. Do you agree that there's nothing on Mutual's
10 Sulindac label which alerts its readers that someone might
11 have dysphagia or a painful swallowing as a result from
12 taking Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 88:19 - 89:2

THE WITNESS: No, I don't see dysphagia.

20 BY MR. JENSEN:

21 Q. Do you see on the next line where Mutual reported

Bartlett v Mutual

22 to the FDA that Karen had a gastrostomy tube placed?

23 A. Yes, I see that.

24 Q. Do you agree that there's nothing in the Sulindac

25 label where Mutual alerts its readers that someone might
00089

1 need a g-tube or a gastrostomy tube placed if they take

2 Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 89:9 - 89:14

THE WITNESS: I don't see a gastrostomy

10 tube in the insert.

11 BY MR. JENSEN:

12 Q. Do you also agree that Mutual reported to the FDA

13 that Karen had a g-tube for eleven months, from May 2005

14 to April 2006?

Witness_ Andrea Werynski - Vol. 1.txt: 89:19 - 89:24

THE WITNESS: Yes, I see that.

20 BY MR. JENSEN:

21 Q. Do you agree that there's no g-tube mentioned in

22 the label or there's no mention that someone might need a

23 g-tube for an extended period of time, let alone eleven

24 months?

Witness_ Andrea Werynski - Vol. 1.txt: 90:7 - 90:12

THE WITNESS: No, I don't see g-tube

8 in the insert.

9 BY MR. JENSEN:

10 Q. Or for any extended period of time or for any

11 time at all, right?

12 A. Right.

Witness_ Andrea Werynski - Vol. 1.txt: 90:15 - 90:18

Q. Do you see the next sentence where Mutual
16 reported to the FDA that Karen underwent dilatation
17 surgery for her esophagus, which is to enlarge her
18 esophagus due to an esophageal stricture?

Witness_ Andrea Werynski - Vol. 1.txt: Page 90, Line 21

THE WITNESS: Yes, I see that.

Objection (90:15 to
90:21):

-Argumentative
-Foundation

-402

-403

-602

-702

-801

-802

-1002

Ruling: Sustained as to "which is to enlarge
her esophagus due to an esophageal stricture."
Otherwise overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 91:18 - 91:20

Q. Do you agree that there's nothing in the Sulindac

19 label which advises or alerts its reader that they might

20 need an esophageal dilatation or enlargement surgery?

Witness_ Andrea Werynski - Vol. 1.txt: 92:6 - 92:18

THE WITNESS: No, I don't see dilatation

7 of the cervical esophagus.

8 BY MR. JENSEN:

9 Q. Or anything in relation to a dilatation surgery,

10 correct?

11 A. Correct.

12 Q. Do you see at the very bottom there that Mutual

13 reports to the FDA that Karen needed a donor cornea placed

Objection (91:18
to 93:18):

-Argumentative
-Foundation

-402

-403

-602

-702

-801

-802

-1002

Ruling: Overruled.

Bartlett v Mutual

14 in her left eye?

15 A. Yes.

16 Q. Do you agree that there's nothing in the Mutual
17 label regarding the potential need for a donor cornea in
18 any eye if you take Mutual's Sulindac product?

Witness_ Andrea Werynski - Vol. 1.txt: 93:1 - 93:6

THE WITNESS: Donor cornea, I don't see

2 it in the insert.

3 BY MR. JENSEN:

4 Q. Do you agree with me that there's nothing in the
5 Sulindac label that relates to blindness or potential
6 blindness if you take Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 93:16 - 93:18

THE WITNESS: I don't see blindness, but

17 I see disturbance of the retina in the vascular
18 region.

Witness_ Andrea Werynski - Vol. 1.txt: 94:10 - 94:14

Q. Based upon your review of the label, other than
11 disturbances, blurred vision, or visual disturbance, do
12 you agree that there's nothing in the label that alerts
13 the reader that they might be blind as result of taking
14 Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 94:22 - 95:8

THE WITNESS: I don't see the term

23 blindness in the insert.

24 BY MR. JENSEN:

25 Q. Representing to you that Ms. Karen Bartlett had
00095
1 eleven eye surgeries, ten in her left eye, including four
2 karetoprosthesis surgeries in her left eye, and she's had
3 transplanted corneas, including plastic apparatuses in her
4 left eye four times.

5 Do you agree that there's nothing in the
6 Sulindac label that alerts its reader that someone might
7 need multiple eye surgeries to treat the blindness or
8 possible blindness as a result of taking Sulindac?

Witness_ Andrea Werynski - Vol. 1.txt: 95:18 - 95:19

THE WITNESS: I don't see multiple eye

19 surgeries in the insert.

Witness_ Andrea Werynski - Vol. 1.txt: 96:7 - 96:9

Q. Do you agree that there's nothing in the Sulindac
8 label which alerts its readers that SJS or TEN might lead
9 to blindness?

Witness_ Andrea Werynski - Vol. 1.txt: Page 96, Line 17

THE WITNESS: No, I don't see that.

Witness_ Andrea Werynski - Vol. 1.txt: 97:19 - 97:25

Bartlett v Mutual

Q. Is it true that for every condition and treatment
20 that we've gone through today where you testified that
21 such condition, disease, or treatment is not in the
22 label? It's also true that there's nothing in the label
23 that says that if someone gets SJS or TEN, those
24 conditions might lead to any of the matters you identified
25 as not being in the label, correct?

Witness_ Andrea Werynski - Vol. 1.txt: 98:7 - 98:10

THE WITNESS: I'll agree that the terms
8 and treatments that we discussed today, and I
9 said they were not in the insert, and I agree
10 that they're not in the insert.

Objection (97:19
to 98:10):
-Vague
-Ambiguous
-Improper
impeachment
-402
-403

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 99:16 - 99:19

Q. And also, all the terms that we discussed today
17 that you testified were are not in the label are not
18 identified in the label as potentially resulting from SJS
19 or TEN, correct?

Witness_ Andrea Werynski - Vol. 1.txt: Page 100, Line 1

THE WITNESS: Yes, that's correct.

Objection (99:16 to
100:1):
-Vague
-Ambiguous
-Improper
impeachment
-402
-403

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 101:24 - 102:3

Q. And we've gone through a number of matters which
25 were both conditions or diseases and a number of matters
00102
1 which were treatments for conditions or diseases, which
2 you testified are not in the Sulindac label, all within
3 these five pages of Mutual's Med Watch report, correct?

Witness_ Andrea Werynski - Vol. 1.txt: Page 102, Line 6

THE WITNESS: Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 102:10 - 102:22

Do you agree that those matters include:
11 One, prolonged hospitalization; two, coma or drug-induced
12 coma; three, ventilator dependence; four, tracheostomy;
13 five, bronchoscopies; six and seven, Morphine and Versed;
14 eight and nine, Methadone and Ativan; ten, eleven, and
15 twelve, packed red blood cells, Albumin, and Crystalloid;
16 thirteen, presser support; fourteen, hypoalbuminemia;
17 fifteen, airway sloughing, with or without thick, bloody
18 secretions; sixteen, a chest tube; seventeen, a Passy-Muir
19 valve insertion; eighteen, TPN or tube feeds; nineteen, a
20 Foley catheter insertion; and twenty -- let's stop there
21 -- with a blood thinner called Fragmin, or twenty-one, a
22 blood thinner called Coumadin.

Objection (101:24 to
104:3):
-Vague
-Ambiguous
-Improper
impeachment
-402
-403

Ruling: Overruled.

Witness_ Andrea Werynski - Vol. 1.txt: 102:25 - 103:6

THE WITNESS: Is there a question?
00103

1 BY MR. JENSEN:

2 Q. Yes. Those are all matters that we identified as
3 not being in the Sulindac label that Mutual reported to

Bartlett v Mutual

4 the FDA that Karen had or treatment she needed as a result
5 of the conditions or diseases she had, and we counted 21
6 so far, correct?

Witness_ Andrea Werynski - Vol. 1.txt: 103:9 - 103:22

THE WITNESS: You've identified 21 terms

10 that I agree I did not see in the insert.

11 BY MR. JENSEN:

12 Q. Now, 22 would be 60 percent sloughing of the
13 skin. Twenty-three, 24, and 25 were the treatments of
14 Aquacel, Acticoat, and Mepitel. Twenty-six would be the
15 vaginal injury of the vulva being erythematous or
16 desquamated. Twenty-seven would be dysphagia or
17 difficulty swallowing or painful swallowing.

18 Twenty-eight would be a g-tube or a
19 gastrostomy tube, whether it is placed at all or placed
20 for 11 months. Twenty-nine would be the need for an
21 esophageal dilatation or an enlargement surgery. Thirty
22 would be the need to have a donor cornea, correct?

Witness_ Andrea Werynski - Vol. 1.txt: Page 104, Line 3

THE WITNESS: Yes, I agree.

Witness_ Andrea Werynski - Vol. 1.txt: 112:2 - 112:8

Q. Now, 435, 436, and 437 are a citizen's petition,
3 a supplement to a citizen's petition, and another
4 supplement to a citizen's petition by Mutual, correct?
5 A. Yes.

6 Q. Please confirm that all three of those exhibits
7 are signed by Robert Dennery in person whose signature
8 that you referred to earlier.

Objection (112:2 to
112:15):
-402 (as to issue, NDA
products, and timing-
see 112:17)
-403
-Vague
-602

Ruling: Sustained.

Witness_ Andrea Werynski - Vol. 1.txt: 112:14 - 112:15

THE WITNESS: Yes. As far as I can

15 tell, they're signed by Robert Dennery.

Witness_ Andrea Werynski - Vol. 1.txt: 125:1 - 125:12

Q. Have you ever seen the log book entries that
2 pertain to the four no longer existing adverse events, the
3 two on 438 and 439? Did you ever see any of those log
4 book entries?

5 A. Yes.

6 Q. When was the last time you did?

7 A. Probably July 11th and November 9th.

8 Q. Did you create 438 and 439?

9 A. Yes.

10 Q. And the reason you say probably is because you
11 believe those are the dates that you created them?

12 A. Yes.

Witness_ Andrea Werynski - Vol. 1.txt: 144:4 - 144:11

Q. So is it your testimony that Exhibit-438 is all
5 of the adverse events in the 150 milligram ANDA or
6 Sulindac?

7 A. Yes.

8 Q. And that's also your testimony regarding 439 for

Bartlett v Mutual

9 the dates referenced there through July 11th, 2008,

10 correct?

11 A. Yes.

ROBERT DETTERY – AUGUST 29, 2009

Pg: 27 Ln: 15 - 18

Annotation:

27:15 Q. Generic labels for drugs are often
16 found in the Physicians' Desk Reference,
17 too; isn't that true?
18 A. No.

RULING:
Overruled.

OBJECTION: Rule 401.
Rule 403.
Foundation.

Pg: 147 Ln: 18 - 20

Annotation:

147:18 THE WITNESS: Before 2006, we
19 were still considering ourselves a
20 generic company.

RULING:
Overruled.

OBJECTION: Non-responsive.

Pg: 148 Ln: 1 - 2

Annotation:

148: 1 Q. I asked you about conduct and you
2 talked about a generic company.

RULING:
Overruled.

OBJECTION: Improper inclusion of statement of counsel which
cannot possibly be considered evidence or relevant.

Pg: 148 Ln: 13 - 16

Annotation:

148:13 THE WITNESS: Before 2006, as
14 a generic company, we did what was
15 expected of us by FDA and did not
16 perform literature surveillance.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.
Subject of Plaintiff's Motion in Limine No. 7.

Pg: 149 Ln: 8 - 11

Annotation:

149: 8 THE WITNESS: FDA policy, I
9 don't know if you would call it
10 prohibited, but I believe it was
11 actively discouraging that.

RULING:

Sustained.

OBJECTION:

Non-responsive.
Speculation.

Pg: 149 Ln: 14

Annotation:

149:14 Q. Nothing prohibited it, correct?

RULING:

Sustained.

OBJECTION:

No answer.

Pg: 217 Ln: 22

Annotation:

217:22 Q. I understand.

RULING:

Overruled.

OBJECTION:

Improper inclusion of statement of Counsel which cannot possibly be evidence or relevant.

Pg: 221 Ln: 5 - 9

Annotation:

221: 5 Q. Did Mutual receive the approximate

6 RDL at the same time when it acquired

7 the NDA?

8 A. We didn't -- that NDA we developed

9 ourselves. We didn't acquire that NDA.

RULING:

Overruled.

OBJECTION:

Rule 401.

Rule 403.

Pg: 223 Ln: 4 - 11

Annotation:

223: 4 Q. Do you have any information as to

5 whether the FDA is actively considering

6 it or when it is estimating or when you

7 are estimating they might decide?

8 A. They acknowledged receipt of it,

9 but other than that, we have no

10 information of what their timing is to

11 be.

RULING:

Sustained.

OBJECTION:

Rule 401.

Rule 403.

Pg: 224 Ln: 2 - 11

Annotation:

224: 2 Q. Then describe for us, please, what
3 enhanced or additional risk information
4 regarding this disorder that Mutual has
5 now got approved through its action?
6 A. Well, nothing is approved yet,
7 but what --
8 Q. Well, it's approved because 30
9 days have passed and it's effective.
10 A. It's effective, but not
11 technically approved.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.

Pg: 229 Ln: 5 - 7

Annotation:

229: 5 THE WITNESS: Yes. We can
6 only do it for NDAs, and we haven't done
7 it for any of our other NDA products.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.

ROBERT DETTERY – SEPTEMBER 1, 2009 (VOL. 2)

Pg: 273 Ln: 20 - Pg: 274 Ln: 8

Annotation:

273:20 Q. Understanding what you just told
21 me, that you are not an expert in the
22 benefit/risk ratio of a product, do you
23 have an understanding that, in fact,
24 benefit/risk ratios can change, either,
25 for example, when a new indication has
274: 1 been discovered, which I think is fair
2 to describe as a new benefit, or when
3 new risk information is learned, or
4 increased incidents risk information is
5 learned that can be described as a new
6 information regarding a risk, hence,
7 changing in any of those examples the
8 risk/benefit profile?

RULING:

Sustained.

OBJECTION:

No Answer.

Pg: 275 Ln: 13 - 18

Annotation:

275:13 Q. I'm not asking you about any other
14 person than you, Mr. Dettery.
15 Isn't it true that Mr. Dettery
16 knows that the benefit/risk profile of a
17 drug can change over the lifetime of the
18 drug?

RULING:

Sustained.

OBJECTION:

No Answer.

Pg: 328 Ln: 16 - 18

Annotation:

328:16 THE WITNESS: The reason that
17 Mutual did that for Qualaquin was
18 because we were the branded product.

RULING:

Sustained.

OBJECTION:

Non-responsive.

Pg: 328 Ln: 25 - Pg: 329 Ln: 3

Annotation:

328:25 branded. I said, was it for post-
329: 1 marketing drug safety reasons?
2 A. As a branded product, that's why
3 we do it, yes.

RULING:

Sustained.

OBJECTION:

Incomplete question.
Non-responsive.

Pg: 335 Ln: 8 - 11

Annotation:

335: 8 THE WITNESS: Yes. Again,
9 it's what you highlighted. I don't know
10 what is in the rest of the document. I
11 haven't seen this document before.

RULING:

Overruled.

OBJECTION:

Non-responsive.

Pg: 347 Ln: 16 - 18

Annotation:

347:16 THE WITNESS: Well, this is
17 the first time I have seen this
18 document, but that is what it appears

RULING:

Overruled.

OBJECTION:

Non-responsive before "...that is..."

Pg: 363 Ln: 3 - 7

Annotation:

363: 3 THE WITNESS: Well, since I
4 haven't seen this since -- let me
5 rephrase.
6 Since I have not seen this
7 before last Friday, I don't know if this

RULING:

Overruled.

OBJECTION:

Non-responsive before "...I don't know".

Pg: 366 Ln: 1 - 2

Annotation:

366: 1 THE WITNESS: I haven't seen
2 this document before. The sentence says

RULING:

Overruled.

OBJECTION:

Non-responsive before "The sentence..."

Pg: 368 Ln: 20 - 23

Annotation:

368:20 THE WITNESS: I see the
21 sentence that you have highlighted. I
22 haven't seen the entire article. But
23 what you stated is what the highlighted

RULING:

Overruled.

OBJECTION:

Non responsive before, "what you stated".

Pg: 390 Ln: 24 - Pg: 391 Ln: 2

Annotation:

390:24 THE WITNESS: Well, in
25 reading this document for the first
391: 1 time, I see sulindac is included in
2 about two dozen products, correct.

RULING:

Overruled.

OBJECTION:

Non-responsive beginning with, "included".

Pg: 394 Ln: 5 - 7

Annotation:

394: 5 THE WITNESS: Well, based on
6 my examining this particular table for
7 the first time, it shows -- it appears

RULING:

Overruled.

OBJECTION:

Non-responsive before "it appears".

Pg: 397 Ln: 18

Annotation:

397:18 A. That is FDA's assumption, correct.

RULING:

Sustained
(Rules 401,
402, 602)

OBJECTION:

Non-responsive other than "correct".
Speculation.

CLAUS DOHLMAN – SEPTEMBER 10, 2009

Pg: 6 Ln: 21

Annotation:

6:21 Q. And I occasionally ask real long questions.

RULING:

Overruled.

OBJECTION:

Improper inclusion of statement of counsel which cannot possibly be evidence or testimony.

Pg: 25 Ln: 24 - Pg: 26 Ln: 5

Annotation:

25:24 Obviously, Stevens-Johnson syndrome doesn't

25 cause legal blindness every time someone

26: 1 has SJS. Correct?

2 A. Does not cause?

3 Q. Does not cause it every time someone has

4 SJS.

5 A. Oh, no. No, no.

RULING:

Sustained.

Improper opinion from non-retained
expert (Fed. R. Civ. P. 26)

OBJECTION:

Rule 401.

Rule 403.

Pg: 27 Ln: 11 - Pg: 28 Ln: 4

Annotation:

27:11 Q. Okay. Medically speaking, Doctor Dohlman,
 12 briefly, what is a mechanism of action?
 13 A. Well, that is something that I really
 14 cannot comment on. I have no expertise
 15 here in the biology of Stevens-Johnson or
 16 epidemiology or statistical correlation
 17 with medications and so on.
 18 Q. Okay.
 19 A. All that I know is vague medical hearsay.
 20 And some people, and I am sure this will
 21 come up later, but some people swear by
 22 medications and, and that can trigger
 23 Stevens-Johnson. Other people are more apt
 24 to blame occasional diseases such as flu or
 25 herpes or something like that that's a
 28:1 trigger mechanism. But here it's I have
 2 no, no expertise in this.
 3 MR. JENSEN: Okay. Nonresponsive.
 4 Q. You very clearly answered my question. You

RULING:

Sustained.

Improper opinion from non-retained
 expert (Fed. R. Civ. P. 26).

OBJECTION:

Rule 401.

Rule 403.

Pg: 42 Ln: 18 - Pg: 44 Ln: 5

Annotation:

42:18 words, tears still functioning.
 19 Q. Okay.
 20 A. And it might be even have been Mrs.
 21 Bartlett. I don't know.
 22 But that is roughly what -- I
 23 think Ms. Bartlett was a little more
 24 inflamed, but that was the type of
 25 operation we did with Mrs. Bartlett.
 43: 1 Because she had still a wet eye, she was
 2 very vulnerable and prone to breakdown and
 3 so on, but the eye was wet.
 4 Q. Right.
 5 A. So we did not have to go to a much more
 6 stymying and ugly and cosmetically
 7 unacceptable Type 2.
 8 Q. Right. You raised, you raised a question
 9 of whether this might be Ms. Bartlett.
 10 Is it correct that a couple pages
 11 later you have a list of the ages of the 16
 12 people that you did this publication about?
 13 A. Okay.
 14 Q. Yes. And Ms. Bartlett is now 50 because
 15 she was born in 1959. And this publication
 16 was in -- she had -- 2007. When your paper
 17 was accepted it was 2007, and she would
 18 have been 48.
 19 A. I-4.
 20 Q. Yes. And that is 46. But I also noticed
 21 that the time period on the very first
 22 page, January 2000 through December 2005,
 23 and your first surgery on Ms. Bartlett was
 24 in 2006. Correct?
 25 A. Oh, I see. Yes, that is correct.
 44: 1 Q. So fair to say that Ms. Bartlett --
 2 A. May not be here.
 3 Q. -- for better or worse, would not have been
 4 one of these 16 patients of yours.
 5 Correct?

RULING:

Overruled.

OBJECTION:

Incomplete answer.
 Rule 401.
 Rule 403.

Pg: 49 Ln: 19 - Pg: 50 Ln: 4

Annotation:

49:19 Q. In terms of medical stratification of
 20 preoperative diagnoses and assessing from
 21 that what the likely outcomes are going to
 22 be after one or more K-Pro's, do you and
 23 your colleagues at Harvard refer to SJS TEN
 24 cases as hopeless cases?
 25 MR. COSGROVE: Objection. Form.
 50: 1 Foundation. Calls for expert testimony.
 2 Beyond the scope of the Doctor's treatment.
 3 A. No. I wouldn't -- I would not call any
 4 case that has light perception hopeless.

RULING:

Sustained.
 Improper opinion from non-retained
 expert (Fed. R. Civ. P. 26).

OBJECTION:

Rule 401.
 Rule 403.

Pg: 65 Ln: 5 - 19

Annotation:

65: 5 Q. Thank you. And so is he again suggesting
 6 that she might need to have both eyes sewn
 7 shut?
 8 MR. COSGROVE: Objection to form.
 9 Foundation.
 10 Q. Is that what that means?
 11 MR. COSGROVE: Same objection.
 12 A. I don't think that he intends to suggest
 13 that both eyes are, will be or should be
 14 completely fully shut. Usually,
 15 tarsorrhaphy is one third out here.
 16 Q. Okay.
 17 A. That's a standard procedure. And in the
 18 worst cases maybe half, but there is always
 19 an opening.

RULING:

Sustained
 (Rules 601 and
 602)

OBJECTION:

Speculation Rule 401.
 Rule 403.

Pg: 96 Ln: 19 - 22

Annotation:

96:19 Q. Can you show us where the ring is of the
20 Boston K-Pro in this diagram you are
21 pointing to?
22 A. The ring cannot be seen here.

RULING:

Sustained.

OBJECTION:

Irrelevant.

Pg: 97 Ln: 7 - 11

Annotation:

97: 7 MR. COSGROVE: Keith, just so I
8 understand for the record, is this Karen's
9 eye?
10 MR. JENSEN: Not to the best of my
11 knowledge.

RULING:

Sustained.

OBJECTION:

Improper inclusion of statement of counsel
which cannot possibly be evidence or
testimony.
Rule 401.
Rule 403.

Pg: 102 Ln: 10 - 13

Annotation:

102:10 Q. Okay. And why do you say it worked well
11 for a while, sir?
12 A. Then Doctor Chodosh will have to continue
13 to answer that.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.

Pg: 116 Ln: 7

Annotation:

116: 7 A. September 19th. I can't see here. Can we

RULING:

Overruled.

OBJECTION:

Irrelevant.

Pg: 120 Ln: 1 - 11

Annotation:

120: 1 Q. Karen has had glaucoma as well, correct?

2 MR. COSGROVE: Objection to form.

3 A. No. She was fortunate enough, in contrast

4 to most other people with Stevens-Johnson,

5 she did not have any real glaucoma. So

6 that was essentially the only aspect that

7 had been, that has gone quite well.

8 Q. Okay.

9 A. That could have been an isolated measure of

10 pressure, a little on the high side, but

11 nothing serious.

RULING:

Overruled.

OBJECTION:

Rule 401.

Rule 403.

Pg: 126 Ln: 22 - Pg: 127 Ln: 1

Annotation:

126:22 Let's look at 212. 212, sir, is a

23 month after that, in May 2008. Do we see

24 -- how is her eye doing at this point, her

25 left eye?

127: 1 A. It seems to be doing fine from here.

RULING:

Sustained.

OBJECTION:

Rule 401.

Rule 403.

Pg: 158 Ln: 18 - Pg: 159 Ln: 9

Annotation:

158:18 Q. Thank you. Is it correct that in our
19 off-the-record conversation the gentleman
20 here, who is running our video machine and
21 doing a wonderful job, asked you whether or
22 not SJS can cause kidney failure?
23 Did he ask you that?
24 MR. COSGROVE: Objection to form.
25 Foundation.
159: 1 A. Yes, it can, right.
2 Q. And what was your --
3 A. But --
4 Q. And what was your answer?
5 A. That is -- that is correct.
6 MR. COSGROVE: Same objection.
7 A. That it can. But I am not familiar with
8 all the numerous systemic complications,
9 including lungs and so on.

RULING:

Sustained.
Improper opinion from non-retained
expert (Fed. R. Civ. P. 26).

OBJECTION:

Rule 401.
Rule 403.
Foundation.

Pg: 160 Ln: 22

Annotation:

160:22 A. Which I took out of our funds here.

RULING:

Sustained.

OBJECTION:

Irrelevant.
Non-responsive.

Pg: 162 Ln: 1 - 10

Annotation:

162: 1 Q. Okay. Why is that your understanding? Is
 2 that from your experience of treating SJS
 3 and TEN patients?
 4 MR. COSGROVE: Objection. Form.
 5 Foundation. Calls for expert testimony.
 6 A. Yes. I have seen a large number of these
 7 patients and I have read the histories and
 8 the evaluation of their referring
 9 physicians and so on. That has given me
 10 certain Gestalt.

RULING:

Sustained.
 Improper opinion
 from non-
 retained expert
 (Fed. R. Civ. P. 26)

OBJECTION:

Rule 401.
 Rule 403.
 Foundation.
 Incomplete answer.
 Rule 26(a)(2)(A)

Pg: 164 Ln: 20 - Pg: 165 Ln: 14

Annotation:

164:20 Q. While all of the reasons may not be
 21 included in this binder, are all of the
 22 opinions that you formulated during your
 23 care and treatment of Ms. Bartlett
 24 contained within this binder?
 25 A. Yes. I don't have any other, other written
 165: 1 opinions, no.
 2 Q. Okay. Am I understanding your testimony
 3 correctly that you have no written opinions
 4 outside this binder --
 5 A. Correct.
 6 Q. -- outside the course and scope of your
 7 treatment of Ms. Bartlett?
 8 A. Correct.
 9 Q. All right. Fair to say that all the
 10 various studies that were marked that were
 11 published both before and after your
 12 treatment of Ms. Bartlett are not included
 13 in this binder. Right?
 14 A. Correct.

RULING:
 Sustained.

OBJECTION: Rule 401.
 Rule 403.

Pg: 166 Ln: 3 - 8

Annotation:

166: 3 Q. Well, what I am getting at here, sir, and
 4 Doctor, and what I would like to confirm is
 5 that you have no opinions beyond Ms.
 6 Bartlett. Correct?
 7 A. Beyond what, what is there, you mean? I
 8 have it up here.

RULING:
 Overruled.

OBJECTION: Rule 401.
 Rule 403.

Pg: 166 Ln: 11 - 15

Annotation:

166:11 Q. In other words, with respect to this case
12 and your involvement in this case as a
13 treating physician of Ms. Bartlett, your
14 opinions do not extend beyond Ms. Bartlett.
15 Correct?

RULING:

Overruled.

OBJECTION:

No answer.
Rule 401.
Rule 403.

Pg: 167 Ln: 14 - 21

Annotation:

167:14 A. I will quote you. But it's as when you
15 treat the patient you go by your own
16 long-term experience, and then you come to
17 a conclusion that is the best chance to be
18 of help is to do so and so. And we will
19 jot down just what we will do, so and so,
20 not the reason why we have -- why I have
21 decided to do it.

RULING:

Sustained.

OBJECTION:

No Question.
Rule 401.
Rule 403.

Pg: 168 Ln: 9 - 25

Annotation:

168: 9 Q. Do you remember when you said that you were
 10 not an expert on SJS and that you would
 11 have very little to add to this?
 12 Do you recall that comment, sir?
 13 A. Well, I should -- I should say I am -- I am
 14 not an expert on the treatment of S -- of
 15 Stevens-Johnson syndrome in general and the
 16 etiology of Stevens-Johnson. This is not
 17 my field.
 18 My field is ophthalmology and the
 19 ophthalmic consequences of Stevens-Johnson
 20 and the ophthalmic treatment.
 21 Q. Sure, the sequelae of Stevens-Johnson,
 22 correct?
 23 A. Correct.
 24 Q. Okay. And you are not, you are not an
 25 infectious disease specialist, right?

RULING:

Overruled.

OBJECTION:

Irrelevant.
 Rule 403.

Pg: 169 Ln: 1 - Pg: 170 Ln: 19

Annotation:

169: 1 A. No.
 2 Q. Now, during the course and scope of your
 3 treatment of Ms. Bartlett, did you have
 4 occasion to review any materials such as
 5 package inserts or labeling generated by
 6 Mutual Pharmaceuticals or United Research
 7 Laboratories?
 8 A. I don't understand. How?
 9 Q. Did you ever have occasion to review the
 10 package labeling for any type of drug or
 11 medication that Ms. Bartlett had taken
 12 prior to her experience, experiencing her
 13 condition in connection with your
 14 treatment?

- 15 A. No. I have not -- I have not searched in
 16 her past what she has been treated with
 17 before she came to me, no.
- 18 Q. Did -- did you ever at any point in
 19 connection with your treatment of Ms.
 20 Bartlett undertake a review of the world
 21 scientific literature for the various
 22 causes of Stevens-Johnson syndrome?
- 23 A. No. I read, I read from time to time the
 24 various hypotheses. But I have restricted
 25 my work and expertise to the treating eye
 170: 1 symptoms. And I cannot comment on etiology
 2 and, and so on.
- 3 Q. Okay. Well, but was the etiology important
 4 to you at all?
- 5 A. Well, it is -- it is important in the sense
 6 that, that they have to be found with
 7 reasonable certainty. And but we cannot do
 8 everything here in life and I will have to
 9 restrict myself to ophthalmology. And when
 10 it comes to the etiology, it is a matter
 11 of, of pharmacology, of infectious disease,
 12 of dermatology and epidemiology and so on.
- 13 Q. And pharmacology and infectious disease and
 14 toxicology, those are not issues on which
 15 you are, you would consider yourself an
 16 expert. Right?
- 17 A. Absolutely not, that is right.
- 18 Q. Do you intend to testify in any capacity as
 19 an expert in this case?

RULING:

Sustained.

OBJECTION:

Cumulative.

Rule 401.

Rule 403.

Offers legal conclusion as to what and expert is.

Pg: 171 Ln: 1 - 13

Annotation:

171: 1 A. Well, I would rather not. I would rather,
2 I would rather stay out of it. But I -- I
3 don't know the implications of that. But I
4 -- I don't -- can I be subpoenaed?
5 Q. Other than your chart, reviewing your
6 chart, did you have -- what else did you do
7 to prepare for your deposition today, if
8 anything?
9 A. I, I, I have said essentially what I know
10 about the treatment of Ms. Bartlett's eye,
11 eyes, and the outcomes there.
12 And anything else, I am not
13 prepared to offer any opinion on.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 172 Ln: 9 - 12

Annotation:

172: 9 You would agree that Doctor
10 Chodosh's opinions and his observations are
11 best asked of him, right?
12 A. Yes.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.

Pg: 180 Ln: 20 - 23

Annotation:

180:20 Q. Okay. And do you know who, who the M.D.
21 who signed that, do you recognize that
22 signature?
23 A. No.

RULING:

Sustained.

OBJECTION: Irrelevant.
Rule 403.

Pg: 182 Ln: 4 - 5

Annotation:

182: 4 A. This is not my opinion. I don't have any
5 opinion.

RULING:

Sustained.

OBJECTION: Rule 401.
Rule 403.

Pg: 183 Ln: 6 - 17

Annotation:

183: 6 A. No, not contrary but not, not for it
7 either. We simply don't have any opinion
8 on the -- I certainly don't have any
9 opinion on etiology.
10 This is notoriously difficult to
11 find and --
12 COURT REPORTER: What?
13 THE WITNESS: Notoriously
14 difficult to identify. And I have not been
15 involved with her original hospitalization
16 at MGH and so I cannot comment one way or
17 the other.

RULING:

Sustained.

OBJECTION: Non-responsive after "no".

Pg: 184 Ln: 4 - 17

Annotation:

184: 4 Would you defer to Doctor Schulz,
5 who is Karen's attending burn physician at
6 MGH, on the question of whether or not
7 Sulindac was responsible and caused Karen's
8 SJS and TEN?
9 MR. COSGROVE: Objection. Form.
10 Foundation. Argumentative. Misleading.
11 Misstates facts.
12 COURT REPORTER: Can you say that
13 objection over, please.
14 MR. COSGROVE: Objection. Form.
15 Foundation. Argumentative. Misleading.
16 Misstates facts.
17 A. I cannot comment on this.

RULING:

Sustained.

OBJECTION:

Rule 401.
Rule 403.
Foundation.

NAM KIM DEPOSITION – SEPTEMBER 30, 2009

Pg: 47 Ln: 18 - Pg: 48 Ln: 13

Annotation:

47:18 Q. Tell us about the relationship between -- strike
19 that. If I was to say: Doctor, if a person is
20 sedated, they don't need pain medication because they
21 can't feel anything, what's your response to that?
22 A. Sedation is not the same as treatment of pain.
23 Q. Okay. Do people -- does the -- do you believe
24 that when you were treating Karen Bartlett, she was
25 feeling pain even when sedated?

48: 1 MR. GEOPPINGER: Objection; form,
2 foundation.

3 THE WITNESS: I can't say. I don't
4 know. The pain medications address the
5 pain. The sedation addresses anxiety, or
6 we call them anxiolytics as well, they
7 address the anxiety. It can cause a
8 disassociation from the pain, but treatment
9 with sedation does not necessarily or --
10 treat pain and I think that's something
11 that a lot of people become confused with.
12 But you have to treat pain and you have to
13 treat anxiety.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.
Speculation.

Pg: 55 Ln: 2 - 8

Annotation:

55: 2 Q. So on this chart, Exhibit 141, the only blood
3 transfusions are the packed red blood cells and the
4 fresh frozen plasma, correct?

5 MR. GEOPPINGER: Objection to form.

6 THE WITNESS: The fresh frozen plasma
7 is not a blood transfusion. It's a blood
8 product.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 80 Ln: 3 - 6

Annotation:

80: 3 Q. Would you have usually in the course of your
4 care and treatment of Karen Bartlett had been reading
5 the notes of Dr. Schultz and Dr. Ryan and Dr. Sheridan?
6 A. Sometimes.

RULING:

Overruled.

OBJECTION: Rule 401.
Rule 403.

Pg: 80 Ln: 24 - Pg: 81 Ln: 3

Annotation:

80:24 Q. Do you remember a Dr. Ken Shepherd at Mass
25 General who did a RICU consult for Karen Bartlett about
81: 1 four days after this note, and I'll show it to you in a
2 second?
3 A. No, I don't remember.

RULING:

Sustained
(assumes facts
not in evidence)

OBJECTION: Rule 401.
Rule 403.

Pg: 82 Ln: 4 - 19

Annotation:

82: 4 Q. And I use the word "recommended." Would it be
5 more accurate to state that you made decisions about
6 what medications Karen should get and the dosages she
7 should get and how often she should get them?

8 A. Well, for narcotic drips often we write the
9 order for a drip and give a range, and then what
10 happens is the people at the bedside, the nurses, will
11 make the assessment and titrate it to effect.

12 Q. And what does titrate mean, please?

13 A. Meaning -- well, it is -- titrate is, well, if
14 she looks like she's in pain, then you would increase
15 the drip. If it looks like she's overly narcotized,
16 meaning that she's not responsive, then they would turn
17 it down. So for these decisions, titrating a drip up
18 and down, as long as it's not beyond a normal range,
19 the nurses would -- would do themselves.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 87 Ln: 24 - Pg: 88 Ln: 1

Annotation:

87:24 Q. Thank you. On two days later on March 16, '05,
25 can you please tell us in lay terms what's going on
88: 1 with your patient then on hospital day 41.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.
No Answer.

Pg: 92 Ln: 12 - 20

Annotation:

92:12 THE WITNESS: Well, it actually, if
13 -- in the latter part of these notes, it
14 appears that I'm now saying:
15 Hospitalization day and not ICU day and I
16 don't mention any critical care time. So I
17 would say typically these -- that was
18 probably shorter amounts of times and she
19 must have fallen off the critically ill
20 list sometime during the latter part of her

RULING:

Overruled.

OBJECTION:

No Question.
Incomplete Answer.
Rule 401.
Rule 403.

Pg: 94 Ln: 7 - 15

Annotation:

94: 7 Q. Okay. Do you think you would have highly likely
8 read what appeared above your page -- strike that. Do
9 you think it's highly likely you would have read the
10 entry that appears above your writing on that page of
11 the infectious disease note?
12 MR. GEOPPINGER: Objection; form.
13 Q. (By Mr. Jensen) Before you made your entry?
14 MR. GEOPPINGER: Objection; form.
15 THE WITNESS: 50/50.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 94 Ln: 23 - 24

Annotation:

94:23 THE WITNESS: Yes but he makes no --
24 he makes no new recommendations.

RULING:

Overruled.

OBJECTION:

Non-responsive.
Rule 401.
Rule 403.

Pg: 96 Ln: 3 - 4

Annotation:

96: 3 it -- there was no recommendations that
4 would affect us to change our management.

RULING:

Overruled.

OBJECTION:

No question.
Incomplete answer.
Rule 401.
Rule 403.

Pg: 96 Ln: 15 - 17

Annotation:

96:15 Q. Do you remember what was going on at the time in
16 relation to that note, Doctor?
17 A. No, I don't.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 105 Ln: 14 - 16

Annotation:

105:14 Q. Okay. And do you believe at that time that
15 would have been a direct or indirect consequence of
16 Karen's TEN?

RULING:

Overruled.

OBJECTION:

No Answer.
Rule 401.
Rule 403.

Pg: 106 Ln: 9 - 10

Annotation:

106: 9 very poor nutrition. There's -- you can't pinpoint it
10 to one single cause.

RULING:

Overruled.

OBJECTION:

No Question.
Incomplete answer.
Rule 401.
Rule 403.

Pg: 123 Ln: 19 - 25

Annotation:

123:19 Q. Do you recall what month and year you were last
20 at Mass General, please, Dr. Kim?
21 A. I thought it was May.
22 Q. Of 2005 or '6?
23 A. 2005 or '6. You have my CV.
24 Q. Here it is.
25 A. May 2005.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 126 Ln: 2 - 15

Annotation:

126: 2 Q. Do you agree as of 2005 that if, hypothetically,
3 anyone was getting TENS from Chinatown food or from
4 food in Boston in general, it would have been, if
5 known, a public health epidemic?
6 MR. GEOPPINGER: Objection; form,
7 foundation, requests improper expert
8 testimony.
9 THE WITNESS: No because TENS is rare
10 anyways. A lot of people get medications
11 and a vast majority won't have reactions.
12 So it can be true, even if in the remote
13 possibility that Chinese food is involved,
14 that it may be a very rare individual that
15 is impacted just like in the medication.

RULING:

Overruled.

OBJECTION:

Rule 401.
Rule 403.

Pg: 132 Ln: 23 - Pg: 134 Ln: 25

Annotation:

132:23 Q. And correct me if I'm wrong, but did I
 24 understand you to testify earlier that the information
 25 in the history of present illness regarding the biopsy
 133: 1 and the statements regarding NSAIDs and Chinese food,
 2 to your understanding, came from Ms. Morton's review of
 3 records from New England Medical Center?
 4 A. Yes. Not necessarily from the records at New
 5 England Medical Center. What happens is every time a
 6 patient is transferred from one facility to another
 7 facility, someone creates an admission history and
 8 physical, and that admission history and physical will
 9 include a history of present illness. And that --
 10 likely this is very similar to what her admission
 11 history and physical said.
 12 Q. And you're speaking of the admission history and
 13 physical --
 14 A. From Mass General Hospital.
 15 Q. -- created at Mass General. You have to say yes
 16 or no.
 17 A. Sorry. Yes.
 18 Q. And the information in the admission history and
 19 physical would come from the previous hospital from
 20 where she was transferred, correct?
 21 A. It would most, you know, most likely be created
 22 by someone at the accepting facility, in this case Mass
 23 General Hospital, and would be derived from the records
 24 sent with the patient as well as from a verbal sign-out
 25 from the -- a practitioner that was taking care of her
 134: 1 before.
 2 Q. Okay. Is it a fair statement, you can't tell
 3 me, assuming this information in the history of present
 4 illness included in her discharge summary from 4/14/05,
 5 assuming that came from the admission and physical done
 6 at Mass General based upon the information from New
 7 England Medical Center, fair statement you can't tell
 8 me specifically who it was who provided that
 9 information from New England Medical Center?
 10 A. No, not unless -- unless you have records that
 11 specifically say: Information was obtained from so and
 12 so, and they had an actual copy of the transfer summary
 13 from the other facility.
 14 Q. It wasn't you who provided the information on
 15 admission to Mass General?

16 A. I don't think I was involved with her on her
 17 admission. I think I was involved shortly thereafter
 18 but not on her admission.
 19 Q. Doctor, if you would take a look at Exhibit, I
 20 believe it's 136, which is a compilation of your notes
 21 from your treatment of Ms. Bartlett --
 22 A. Okay.
 23 Q. -- during her first admission at Mass General,
 24 correct?
 25 A. Mm-hmm.

RULING:

Overruled.

OBJECTION:

Rule 401.
 Rule 403.

Pg: 134 Ln: 25 - Pg: 145 Ln: 5

Annotation:

134:25 A. Mm-hmm.
 135: 1 Q. We've gone through those in quite some detail
 2 today, and correct me if I'm wrong, but is it a fair
 3 statement to say that nowhere in this exhibit did you
 4 make any notation regarding NSAIDs being a triggering
 5 or a hypothetical cause of Ms. Bartlett's TENS?
 6 A. I don't think I have put it there, you know,
 7 without reviewing everything, but it wouldn't -- it
 8 wouldn't be something that I would note because it's
 9 not an event and it's not a new allergy. It's not
 10 anything new that's happened since her admission. So
 11 it's very likely I may not have mentioned anything.
 12 Q. Okay. As we sit here today, you can't point me
 13 to anything that I missed --
 14 A. No.
 15 Q. -- because I believe I've read it.
 16 A. I can't --
 17 Q. Obviously it's your handwriting and --
 18 A. I can't pinpoint anything at this, you know,
 19 maybe if I took a microscope, maybe I could find
 20 something. But from my review, I would say that no.
 21 Q. Thank you. Doctor, is it a fair statement to
 22 say that your primary concern with respect to
 23 Ms. Bartlett is providing treatment for her TENS,
 24 correct?
 25 A. Yes.
 136: 1 Q. Your primary concern during her hospitalization

2 and during the course and scope of your treatment is
3 not to determine the etiology of her TENS, correct?

4 A. It is not to determine the etiology. It is --
5 except for the fact that we have to stop exposure to
6 it. But no. If we believe we've stopped exposure to
7 it, it's not something that I would spend a lot of time
8 investigating.

9 Q. Is it a fair statement to say that in the
10 interest of stopping exposure to potential reasons for
11 TENS, you're overly cautious in that respect?

12 A. You mean like prescribing the other drugs in the
13 same classification or with similar chemical
14 structures?

15 Q. What I mean is that in the interest of making
16 sure that you don't expose the patient to any potential
17 or hypothetical or possible reason why they had
18 initially contracted the TENS, that you're going to be
19 -- would it be fair to say that you're overly cautious
20 in that regard?

21 A. Well, we don't like to be overly but we like to
22 be reasonably cautious --

23 Q. All right. Fair.

24 A. -- okay, because you can rule out all sorts of
25 drug classes if you say that everything potentially
137: 1 could be causing it. So we would like to be reasonably
2 cautious and make sure that the most likely culprits
3 are at least she's not exposed to again.

4 Q. Right. And when you say, "the most likely
5 culprits," is it a fair statement that your
6 determination, if you made one, that the most likely
7 culprit in this case would be the use of an NSAID was
8 based upon her history and physical, correct?

9 A. It would be based on her history. Her physical
10 would give you no clue.

11 Q. Okay. And her history was what?

12 A. Her history was that she came in from New
13 England Medical Center with biopsy-proven TENS after
14 exposure to sulindac and eating Chinese food.

15 Q. And when -- another way of saying exposure to
16 sulindac is that she had taken sulindac in temporal
17 proximity to the diagnosis of TEN, correct?

18 A. Yes.

19 Q. Other than that temporal proximity, did you do
20 any type of experiment or any other type of process by
21 which to attempt to determine that --

22 A. No.

23 Q. -- sulindac had something to do with the TEN?
24 A. No.
25 Q. Doctor, Mr. Jensen mentioned during his
138: 1 questioning that you and he had had a conversation
2 substantively regarding this case and Ms. Bartlett's
3 treatment prior your deposition today, correct?
4 A. Mm-hmm.
5 Q. When did that occur?
6 A. Oh, I can't remember. Like maybe a couple weeks
7 ago, three weeks ago, something two to three weeks ago.
8 Q. Was it in person or on the phone?
9 A. On the phone.
10 Q. What did you discuss?
11 A. This -- this -- we reviewed some of -- some of
12 the other notes. We reviewed the discharge summary.
13 Q. Did Mr. Jensen provide you documents in advance
14 of your telephone conversation?
15 A. Yes. I had PDFs of many of these documents.
16 Q. Can you tell me today as you sit here which
17 documents you had PDFs of?
18 A. I had PDFs of my notes. I had PDFs of some of
19 Dr. Sheridan's notes, some of Dr. Colleen Ryan's notes.
20 I have the PDFs of the discharge summaries, both of
21 them. I think -- I think that's fairly it.
22 There's some PDFs I didn't even open but most of
23 it is because I had no access to any of these notes
24 because I'm not at that facility anymore.
25 Q. Did you have any PDFs of medical literature?
139: 1 A. I have a PDF of just the gross summarization of
2 some of them.
3 Q. Is that a PDF that was provided to you by Mr.
4 Jensen?
5 A. Yes.
6 Q. Did you review that prior to coming to your
7 deposition today?
8 A. Just briefly, yeah.
9 Q. And did you review the records, the medical
10 records, that he provided you before coming to your
11 deposition?
12 A. Not today but I did before our -- some of --
13 some of them before the conversation with him and some
14 during our conversation.
15 Q. Fair to say that you -- any information you
16 provided -- excuse me, strike all that. It's fair to
17 say that any information Mr. Jensen provided to you,
18 you have reviewed within, say, the last month?

19 A. Yes.

20 Q. Are you relying upon that information for your
21 deposition testimony here today?

22 A. Yes. For the medical records I am because I
23 don't have access to them.

24 Q. I think you mentioned you reviewed medical
25 records that were made by physicians other than
140: 1 yourself, correct?

2 A. Some of them but not as in depth as to my own.

3 Q. Did you review any medical records that were
4 made by -- well, strike that. Did you review any
5 medical records at all that were made regarding Karen
6 Bartlett that were made after the last time you treated
7 her?

8 A. I saw the discharge summary that was signed by
9 Dr. Schultz.

10 Q. And do you recall -- are you speaking of the
11 second discharge summary from Massachusetts General?

12 A. Yes.

13 Q. Okay. Did you review any medical records that
14 were made after that?

15 A. No. At least I don't think so.

16 Q. Now, during the course of your discussion with
17 Mr. Jensen, did you discuss the fact that this
18 litigation exists?

19 A. Yes.

20 Q. Obviously you wouldn't have been talking with
21 him otherwise, correct?

22 A. Right.

23 Q. You didn't know Mr. Jensen personally --

24 A. Nope.

25 Q. -- before this litigation?

141: 1 A. I did not know him.

2 Q. During the course of your discussion, you
3 discussed Ms. Bartlett's treatment, correct?

4 A. Yes.

5 Q. Anything else that you discussed?

6 A. Well, we discussed blood products because he
7 didn't have a clear understanding of what exactly were
8 blood products and why they were used.

9 MR. JENSEN: That does not call for
10 speculation. That's stipulated.

11 THE WITNESS: We discussed Chinese
12 food but that's pretty much about it.

13 Q. (By Mr. Geoppinger) Did you discuss the nature
14 of the claims in this case?

15 A. My understanding is that -- we actually didn't,
16 but my understanding of this was that, essentially, the
17 drug company is being sued for -- as the cause of the
18 -- Ms. Bartlett's TENS.

19 Q. Where did you gain that understanding?

20 A. From the whole fact that this is going on
21 because when I got the -- when I was contacted, it was
22 like, well, the first thing we think is, well, we're
23 being sued. And so essentially I was told that the
24 providers are not being sued. It's the drug company
25 that is being sued.

142: 1 Q. Right. Did -- in the course of your discussion,
2 was there any discussion that the drug company was
3 being sued because the product was superpotent or there
4 was something wrong with the manufacture of the product
5 or was there any specifics in the discussion --

6 A. No.

7 Q. -- about why in fact this lawsuit had been filed
8 in that respect?

9 A. Actually, no.

10 Q. Okay. All right. Earlier in your deposition
11 today, you made some reference to a mechanism of action
12 for TENS. Do you recall that testimony?

13 A. Not exactly but was it something about the
14 adhesion?

15 Q. Well, let me ask you this: In 2005 during the
16 course and scope of your treatment of Karen Bartlett,
17 did you have any information about the mechanism of
18 action by which any compound could --

19 A. I don't think --

20 Q. -- lead to TEN?

21 A. I don't think it's well understood. We believe
22 that it's -- it is partially immunological but it's
23 not -- my understanding, it's not clearly understood
24 exactly why medications may cause TENS. In fact, it's
25 also not understood exactly why some stay

143: 1 Stevens-Johnson's, which means that it's 30 percent or
2 less and why some progress to greater than 30 percent
3 and it's considered TENS. So it is rare enough that is
4 not particularly well understood which is why some of
5 these -- these treatments are not done because
6 they're -- they're not known to cause benefit.

7 Q. So fair statement, though, with respect to my
8 question, at the time you treated Karen Bartlett, fair
9 that you -- you're not going to testify you had an
10 understanding of the mechanism by which sulindac or any

11 medication for that matter --

12 A. No.

13 Q. -- could lead to TENS?

14 A. We had a basic understanding of TENS that you
15 would learn in residency and medical school.

16 Q. Doctor, you also -- I believe you also testified
17 today that TENS is a rare condition, correct?

18 A. Yes.

19 Q. At the time you were treating Karen Bartlett,
20 did you believe that TENS was a rare condition?

21 A. Yes.

22 Q. Are you familiar with the word "idiosyncratic"?

23 A. Yes.

24 Q. On the assumption that TENS could result from a
25 reaction to any medication, in 2005 would it have been
144: 1 your analysis that TENS from any medication would be an
2 idiosyncratic reaction to that medication?

3 MR. JENSEN: Assumes facts not in
4 evidence.

5 THE WITNESS: It's possible. The
6 problem with idiosyncratic is that as we
7 know more, we learn that a lot of
8 idiosyncratic stuff is not idiosyncratic.
9 So idiosyncratic just means we don't know
10 typically in medicine. So...

11 Q. (By Mr. Geoppinger) I think you answered my
12 question but I'm going to ask it again just to see if I
13 can get a clear record. In 2005 would you have
14 considered a reaction of TENS to any medication to be
15 an idiosyncratic reaction to that?

16 MR. JENSEN: Assumes facts not in
17 evidence that all medications cause TENS.

18 THE WITNESS: It's -- once again,
19 it's like for us idiosyncratic means that
20 we just don't know enough. I mean, there
21 can be a genetic basis. We don't know. So
22 it's a rare reaction that's uncommon that
23 some people may or may not be susceptible
24 to. I guess I just can't answer that
25 question.

145: 1 Q. (By Mr. Geoppinger) Sure. Okay. Well, let me
2 see if I can rephrase it. Would you agree or disagree,
3 if you like, but would you agree that a person who
4 develops TENS from allegedly any medication -- strike
5 all that. Is there an identifiable class of people who

RULING:

Sustained as to lines 141:6
through 141:10 and lines 141:13
through 142:9.

OBJECTION:

Rule 401.
Rule 403.

Otherwise overruled.

Pg: 146 Ln: 11 - Pg: 148 Ln: 1

Annotation:

146:11 Q. The medical records that you received -- you did
12 receive medical records from Mr. Jensen?

13 A. Yeah. I received initially some of my stuff. I
14 received the, I believe, the ID consult of one of the
15 ID docs. I received the discharge summary of
16 Dr. Schultz and then I had to ask for my own because
17 they -- someone asked me about my own and I'm going:
18 Well, I don't have it. So...

19 Q. Fair to say you didn't receive the entirety of
20 the Massachusetts General --

21 A. I didn't receive --

22 Q. -- medical record from her hospitalization in
23 2005?

24 A. I didn't receive the entirety of it.

25 Q. Who selected the portions to give you?

147: 1 A. He or one of his assistants or one of his
2 colleagues did.

3 Q. He meaning Mr. Jensen?

4 A. Yes.

5 Q. You didn't specifically request only portions of
6 the medical record?

7 A. No but I did request -- I did request at least
8 some of my records so that I knew what I had said.

9 Q. Sure. But with respect to other physicians, you
10 didn't identify --

11 A. No.

12 Q. -- particular physicians who you wanted and who
13 you didn't?

14 A. No, I didn't.

15 Q. You referenced a summary of medical literature
16 that you received in advance of your deposition; is
17 that correct?

18 A. Yeah. It was just a list of papers.

19 Q. How many pages was that document?

20 A. Like one and a quarter, one and a half.

21 Q. Do you know who created that document?

22 A. I believe Mr. Jensen may have but I'm not
23 absolutely sure.

24 Q. Did you read any of the papers referenced on
25 that document before you came here today?

148: 1 A. No.

RULING:

Overruled.

OBJECTION:

Rule 401.

Rule 403.

ANDRIA WERYNSKI DEPOSITION – SEPTEMBER 1, 2009

Pg: 75 Ln: 13

Annotation:

75:13 A. Outside of the RLD update.

RULING:

Overruled.

OBJECTION: No question.

ANDRIA WERYNSKI DEPOSITION – (VOL.2) – NOVEMBER 13, 2009

Pg: 66 Ln: 10 - 12

Annotation:

66:10 THE WITNESS: Hospitalization is not an
11 adverse event. So it wouldn't be expected to be
12 on the label.

RULING:

Sustained.

OBJECTION: Non-responsive (the question didn't ask for an opinion as to what should be in the label or why). Undesignated opinion. Rule 26(a)(2)(A).

Pg: 67 Ln: 8 - 12

Annotation:

67: 8 THE WITNESS: I can't look at the label
9 and know if there is a term that should mean
10 coma. I can look at the label to see if it says
11 coma, but there are many other terms that could
12 be associated with that.

RULING:

Overruled.

OBJECTION: Non-repsonsive.

Pg: 71 Ln: 7 - 8

Annotation:

71: 7 A. Yes. But again, I'm not qualified to understand
8 if those terms are represented in this label.

RULING:

Overruled.

OBJECTION: No question.

Pg: 71 Ln: 11 - 12

Annotation:

71:11 Q. I'm not asking for your medical opinion. I'm
12 asking you whether they are in the label or not.

RULING:

Overruled.

OBJECTION: No answer and incomplete question.

Pg: 73 Ln: 9 - 11

Annotation:

73: 9 Q. Okay. And Mutual recorded there that based upon
10 their evaluation or Prosar's evaluation that Ms. Bartlett
11 needed five bronchoscopies, correct?

RULING:

Sustained.

OBJECTION: Calls for speculation.

Pg: 73 Ln: 15 - 17

Annotation:

73:15 THE WITNESS: These are just copies of
16 her medical records. So I don't know why you
17 would say Prosar inferred that.

RULING:

Sustained.

OBJECTION: Non-responsive.

Pg: 75 Ln: 9 - 10

Annotation:

75: 9 THE WITNESS: It's not the type of
10 information that would be in a label.

RULING:

Sustained.

OBJECTION: Undesignated opinion. Rule 26(a)(2)(A). And, no question designated.

Pg: 77 Ln: 11

Annotation:

77:11 THE WITNESS: Anemia is in the insert.

RULING:

Overruled.

OBJECTION: Irrelevant.

Pg: 77 Ln: 13 - 15

Annotation:

77:13 Q. Thank you. Where did you find that?
14 A. On Page 2 under hematologic aplastic anemia,
15 hemolytic anemia.

RULING:

Overruled.

OBJECTION: Irrelevant.

Annotation:

91: 8 THE WITNESS: Well, this says that she
9 underwent dilatation of the esophagus due to
10 stricture formation related to SJS, and SJS
11 is in the insert.

RULING:

Overruled.

OBJECTION: Non responsive (question asked about label answer spoke of medical records).

Pg: 91 Ln: 14 - 17

Annotation:

91:14 Q. Are you going to answer the question or do you
15 want me to repeat it?
16 A. Do I see that she underwent dilatation of her
17 esophagus due to stricture formation in the insert?

RULING:

Overruled.

OBJECTION: Irrelevant. Non-responsive. A question answering a question is not evidence.

Pg: 98 Ln: 21 - 24

Annotation:

98:21 THE WITNESS: I mean, SJS and TEN is in
22 the insert and it's meant for a physician. So I
23 don't know why you would list the treatments or
24 the conditions that can result in the insert.

RULING:

Sustained.

OBJECTION: Non-responsive and irrelevant answer. Undesignated opinion as she is stating by negative inference that treatments or conditions need not be in the insert. That is an expert opinion. Rule 26(a)(2)(A) & (B).

Pg: 99 Ln: 11 - 14

Annotation:

99:11 THE WITNESS: The label states
12 fatalities may occur in these patients with SJS.
13 I'll agree that the terms that we discussed today
14 aren't in there, but there are terms in there.

RULING:

Overruled.

OBJECTION: Non responsive. The question specifically asked about "where the label lists SJS and TEN" which is one paragraph, her answer addressed a different portion of the label.

Pg: 100 Ln: 23 - 24

Annotation:

100:23 THE WITNESS: Are you asking me if
24 prolonged hospitalization is in the insert?

RULING:

Overruled.

OBJECTION: Irrelevant a question responding to a question is not evidence.

Pg: 101 Ln: 16 - 17

Annotation:

101:16 THE WITNESS: I don't know what the
17 questioning is.

RULING:

Overruled.

OBJECTION: Irrelevant. An exchange about what is being asked is probative of nothing and a "waste of time" under 403.

Pg: 105 Ln: 2 - 3

Annotation:

105: 2 THE WITNESS: No, I don't understand
3 what you mean.

RULING:

Overruled.

OBJECTION: Irrelevant. An exchange about what is being asked is probative of nothing and a “waste of time” under 403.

Annotation:

105:15 THE WITNESS: Yes, but then again, I'm
16 not qualified to do that.

RULING:

Overruled.

OBJECTION: Non responsive after “Yes”.

Pg: 106 Ln: 1 - 2

Annotation:

106: 1 foundation, confusion.
2 THE WITNESS: Yes.

RULING:

Overruled.

OBJECTION: Cumulative and a “waste of time” under 403.

Pg: 106 Ln: 19 - 25

Annotation:

106:19 THE WITNESS: And again, I'll say that
 20 I'm not qualified to interpret the medical terms
 21 in the insert and understand if another term
 22 is covered in the insert. It says peptic ulcer
 23 and gastrointestinal bleeding have been reported.
 24 So I don't know. I'm not qualified to make that
 25 assessment.

RULING:

Overruled.

OBJECTION:

Non responsive.

Pg: 107 Ln: 8

Annotation:

107: 8 THE WITNESS: Gastritis, peptic ulcer.

RULING:

Sustained.

OBJECTION:

**Undesignated expert opinion.
 Rule 26(a)(2)(A) & (B).**

Pg: 107 Ln: 10 - 15

Annotation:

107:10 Q. Is it fair to say you don't know what you just
 11 read covers acid reflex disease or not?
 12 A. That's correct.
 13 Q. Dr. Sandronoori also concluded that Karen has
 14 ARDS or acute respiratory distress syndrome as a result of
 15 her SJS. We have already discussed that, correct?

RULING:

Sustained.

OBJECTION:

Irrelevant.

Pg: 107 Ln: 18 - 19

Annotation:

107:18 THE WITNESS: Well, I don't remember
19 discussing that.

RULING:

Overruled.

OBJECTION: Cumulative and a “waste of time” under 403.

Pg: 107 Ln: 21 - 23

Annotation:

107:21 Q. We discussed it right there on Page 2 of 403. So
22 my question is: Do you see ARDS listed on Page 2 of 403
23 as unexpected event or unlabeled event?

RULING:

Overruled.

OBJECTION: Objection. Answer saying “Yes, we did discuss that is omitted”. If included it is cumulative and a “waste of time” under 403.

Pg: 108 Ln: 14 - 17

Annotation:

108:14 THE WITNESS: That's what I don't
15 understand, if all these things were determined
16 caused by SJS and SJS is in the label, then I
17 don't understand what you're asking.

RULING:

Overruled.

OBJECTION: Irrelevant, cumulative and a “waste of time” under 403.

Pg: 109 Ln: 6 - 7

Annotation:

109: 6 THE WITNESS: I mean, you said that it's
7 caused by SJS. SJS is in the label.

RULING:

Overruled.

OBJECTION: Non responsive.

Pg: 109 Ln: 24 - 25

Annotation:

109:24 THE WITNESS: I don't have anything else
25 to add.

RULING:

Overruled.

OBJECTION: Irrelevant and prejudicial. It is not evidence that the witness chose not to answer a question a second time.

Pg: 110 Ln: 20 - 23

Annotation:

110:20 THE WITNESS: It might be represented
21 within the label by a term that I don't
22 understand. There's respiratory terms in here.
23 I don't know if that means the same thing as what

RULING:

Overruled.

OBJECTION: What "might be" is not more likely than not, hence, irrelevant.

Pg: 111 Ln: 14 - 15

Annotation:

111:14 THE WITNESS: I don't recall what number
15 we're on.

RULING:

Overruled.

OBJECTION: Irrelevant.

Pg: 111 Ln: 17 - 23

Annotation:

111:17 Q. It would be the next one. Fair enough? It would
18 be the next one to where we stopped, fair?

19 A. Yes.

20 Q. And is it also fair that you're not sure whether
21 aspiration bronchiolitis is covered by something in the
22 label or not?

23 A. Yes.

RULING:

Overruled.

OBJECTION: Irrelevant, cumulative, "waste of time" under Rule 403.